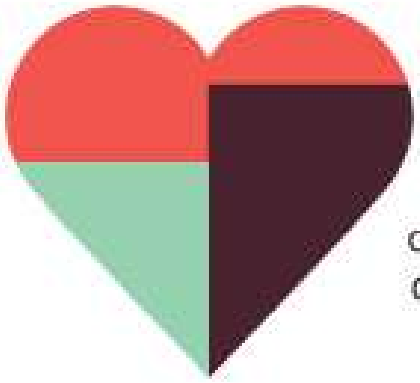

TIGHT K

Prevention of dysrhythmias on the cardiac intensive care unit - does maintenance of high-normal serum potassium levels matter?

Tight K Study

CASE REPORT FORM (CRF)

Tight K Patient ID:	T K
Initials:	
Age in years:	

Sponsored by Barts Health

Funded by the British Heart Foundation

Eligibility and Randomisation

Tight K Patient ID:

T	K					

Initials:

Inclusion Criteria	**YES**	**NO**
1. Scheduled to have isolated CABG surgery		
2. Patient in sinus rhythm		

Answers to both questions must be YES to qualify for the study

Exclusion Criteria	**YES**	**NO**
1. Age less than 18 years		
2. Previous history of Atrial Fibrillation, Atrial Flutter and/or Atrial Tachyarrhythmia		
3. Pre-operative high-degree atrioventricular (AV) block (defined as Mobitz type 2 second degree AV block or complete heart block)		
4. Pre-op serum K+ greater than 5.5 mEq/L		
5. Current or previous use of medication for the purposes of cardiac rhythm management		
6. Dialysis dependent end stage renal failure		
7. Concurrent patient involvement in another clinical study assessing cardiac rhythm post-operative interventions		
8. Unable to provide informed consent		

Answers to questions 1 - 8 must all be NO to qualify for the study

Eligibility and Randomisation

Tight K Patient ID: | T | K | | | | | |

Initials: | | | |

Date informed consent signed | d | d | m | m | y | y | y | y |

Time informed consent signed | h | h | m | m | (24 hr)

Tight K Patient ID: | T | K | | | | | |

Randomisation date: | d | d | m | m | y | y | y | y |

Time of randomisation | h | h | m | m | (24 hr)

Treatment allocation Tight ☐ Relaxed ☐

Patient Identifiers

Tight K Patient ID: | T | K | | | | | |

Initials: | | | |

Patient NHS number | | | | | | | | | | | | |

CHI number (Scottish patients only) | | | | | | | | | | |

Full Date of Birth | d | d | m | m | y | y | y | y |

Baseline Data

Tight K Patient ID:

T	K					

Initials:

Date baseline data collected

d	d	m	m	y	y	y	y

What was their sex at birth? Female ☐ Male ☐ Other ☐

Specify other: _____

Which of the following best describes how they think of themselves now? (some people's gender identity is not the same as how they were described at birth)

Woman	
Man	
Trans woman	
Trans man	
Non-binary (neither male or female)	
Other	

Weight _____ kg

Height _____ cm

Body Mass Index will be calculated automatically on the eCRF

Systolic blood pressure _____ mmHg

Diastolic blood pressure _____ mmHg

Heart rate _____ bpm

Baseline Data

Tight K Patient ID: ***Initials:***

T	K								

Angina status (CCS) 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ Not Known ☐

NYHA class I ☐ II ☐ III ☐ IV ☐ Not Known ☐

Smoking history Current ☐ Ex ☐ Never ☐

Alcohol consumption _____ units per week

euroSCORE II Yes ☐ No ☐ Not Known ☐

euroSCORE II value ☐☐ . ☐☐ %

Has the Patient completed the EQ-5D-5L? Yes ☐ No ☐

Baseline Data (Ethnicity)

Tight K Patient ID: | T | K | | | | | | ***Initials:*** | | | |

White
- British ☐
- Irish ☐
- Any other White background ☐

Mixed
- White and Black Caribbean ☐
- White and Black African ☐
- White and Asian ☐
- Any other mixed background ☐

Asian or Asian British
- Indian ☐
- Pakistani ☐
- Bangladeshi ☐
- Any other Asian background ☐

Black or Black British
- Caribbean ☐
- African ☐
- Any other Black background ☐

Other Ethnic Groups
- Chinese ☐
- Any other ethnic group ☐

- Not stated ☐

Baseline Data (Medical History)

Tight K Patient ID: T K | | | | | | |

Initials: | | |

Hypertension (diagnosed &/or treated)	Yes	☐	No	☐	Not documented	☐
Hypercholesterolemia (diagnosed &/or treated)	Yes	☐	No	☐	Not documented	☐
Vascular disease (other than CAD)	Yes	☐	No	☐	Not documented	☐
Chronic kidney disease	Yes	☐	No	☐	Not documented	☐
Diabetes mellitus	Yes	☐	No	☐	Not documented	☐
If Yes:	Type I	☐	Type II	☐	Not documented	☐
Immediate family history of atrial fibrillation, atrial flutter or atrial tachycardia (grandparents, parents, uncles/aunts, siblings)	Yes	☐	No	☐	Not documented	☐
Previous cerebrovascular event	Yes	☐	No	☐	Not documented	☐
If Yes:						
TIA	Yes	☐	No	☐	Not documented	☐
Stroke	Yes	☐	No	☐	Not documented	☐
If Yes to Stroke:						
Thromboembolism	Yes	☐	No	☐	Not documented	☐
Bleed	Yes	☐	No	☐	Not documented	☐
Previous Myocardial Infarction	Yes	☐	No	☐	Not documented	☐
Previous PCI	Yes	☐	No	☐	Not documented	☐
Previous CABG	Yes	☐	No	☐	Not documented	☐
Congestive Cardiac Failure	Yes	☐	No	☐	Not documented	☐

Baseline Data (Medical History)

Tight K Patient ID: T K

Initials:

LV function measured	Yes	☐	No	☐	Not documented	☐		
Ejection fraction value available	Yes	☐	No	☐				
If Yes, ejection fraction value	_____ %							
If value not known	Good/Normal	☐	Moderate	☐	Poor/Severe	☐		
If Yes, date of evaluation	d d m m y y y y							
Method used	Echocardiogram	☐	MRI	☐	Other	☐		

Right ventricular impairment	Yes	☐	No	☐	Not documented	☐
Mitral Valve disease (moderate/severe)	Yes	☐	No	☐	Not documented	☐
Tricuspid Valve disease (moderate/severe)	Yes	☐	No	☐	Not documented	☐
Left atrial size	Normal	☐	Increased	☐	Not documented	☐

Rheumatic valvular disease	Yes	☐	No	☐	Not documented	☐
COPD	Yes	☐	No	☐	Not documented	☐
Asthma	Yes	☐	No	☐	Not documented	☐
Hyperthyroid	Yes	☐	No	☐	Not documented	☐
Hypothyroid	Yes	☐	No	☐	Not documented	☐
Cirrhosis/liver disease	Yes	☐	No	☐	Not documented	☐

Has the patient had COVID-19? (select one)	Yes – positive test result	☐	No	☐
	Yes – based on symptoms alone	☐	Not sure	☐

Baseline Data (Bloods)

Tight K Patient ID: | T | K | | | | | | | *Initials:* | | | |

Potassium		Date	Value	
K^+				mmol/L

Haemoglobin and Creatinine	Collected? YES	NO	If yes, date	Value	
Hb					g/L
Cr					µmol/L

Estimated GFR	Collected? YES	NO	If yes, date	Value	
eGFR					ml/min/1.73m2

INR	Collected? YES	NO	If yes, date	Value	
INR					

C-Reactive Protein	Collected? YES	NO	If yes, date	Value	
CRP					mg/L

Medications at Baseline

Tight K Patient ID: | T | K | | | | | |

Initials: | | | |

Antiplatelets	YES	NO	NOT KNOWN
Antiplatelets			

β-Blockers	YES	NO	NOT KNOWN
β-Blockers			

ACE Inhibitors	YES	NO	NOT KNOWN
ACE Inhibitors			

Angiotensin Receptor Blockers	YES	NO	NOT KNOWN
Angiotensin Receptor Blockers			

Calcium Channel Blockers	YES	NO	NOT KNOWN
Calcium Channel Blockers			

Digoxin	YES	NO	NOT KNOWN
Digoxin			

Anti-Diabetic Drugs	YES	NO	NOT KNOWN
Insulin			
Non-insulin anti-diabetic drugs (tablets or injections excluding SGLT-2 inhibitors)			
Diet controlled			

SGLT-2 inhibitors	YES	NO	NOT KNOWN
SGLT-2 inhibitors			

f-channel inhibitors	YES	NO	NOT KNOWN
f-channel inhibitors			

Medications at Baseline

Tight K Patient ID:							*Initials:*		
T	K								

Oral Anticoagulants	YES	NO	NOT KNOWN
NOACs/DOAC's (*not* NSAIDS)			
If yes, NOAC/DOAC, was it prescribed specifically because of atrial fibrillation, atrial flutter or atrial tachycardia?			
Warfarin			
If yes, Warfarin, was it prescribed specifically because of atrial fibrillation, atrial flutter or atrial tachycardia?			

Diuretics	YES	NO	NOT KNOWN	
Thiazide Diuretics				
Aldosterone Antagonist				
Loop Diuretics				
Other (If Yes, specify)				

Antianginal Drugs	YES	NO	NOT KNOWN
Antianginal drugs			

Amiodarone	YES	NO	NOT KNOWN
Amiodarone			
If yes, was it prescribed specifically because of atrial fibrillation, atrial flutter or atrial tachycardia?			

Potassium supplements	YES	NO	NOT KNOWN
Potassium supplements			

Statins	YES	NO	NOT KNOWN
Statins			

Surgery details

Tight K Patient ID: ***Initials:***

T	K								

Date of admission to hospital: d d m m y y y y

Was isolated CABG surgery performed as planned: Yes ☐ No ☐

If no, give reason: _____

If yes, date of surgery d d m m y y y y

IMA Yes ☐ No ☐

Number of grafts ☐

Pump status Off pump ☐ On pump ☐

Bypass duration in minutes: ☐☐☐☐ (number of minutes)

Cross-clamp duration in minutes: ☐☐☐☐ (number of minutes)

Further bypass runs Yes ☐ No ☐

More than 30 seconds atrial fibrillation, atrial flutter or atrial tachycardia (during surgery) Yes ☐ No ☐

Other complications Yes ☐ No ☐

If yes, give details: _____

In eCRF ***drop down menu***

Cardioplegia: Yes ☐ No ☐

If no, what method of myocardial protection: _____

If yes, what type of cardioplegia?: Warm blood ☐ Cold blood ☐ Crystalloid ☐

Is the potassium concentration coming off bypass data available? Yes ☐ No ☐

If yes, what was the potassium concentration coming off bypass (mEq/L) ☐

Post-surgery details

Tight K Patient ID: T K | | | | | |

Initials: | | |

Is the patient alive? Yes ☐ No ☐ *If No, please complete a Cause of Death form (page 53)*

If yes, date of admission to ICU/ITU: d d m m y y y y

Time of admission to ICU/ITU: h h m m (24 hr)

Has Holter been fitted (applied to patient's chest) Yes ☐ No ☐

If no, give reason: _____

If yes, date Holter activated d d m m y y y y

Time activated h h m m (24hrs)

If yes, date fitted d d m m y y y y

Time fitted h h m m (24hrs)

Holter monitor ID number | | | | | | - | | | | | |

Have any unexpected adverse events occurred since randomisation? Yes ☐ No ☐ *If Yes, please complete an SAE or NSAE form*

Please see the Safety Reporting section of the protocol for a list of expected adverse events that **do not need to be reported.*

Period 1 (0-24Hrs)

Tight K Patient ID: | T | K | | | | | |

Initials: | | | |

Start date Period 1: d d m m y y y y

Start time of period 1: h h m m (24 hr) *Time patient was transferred to ICU/ITU after surgery*

End date Period 1: d d m m y y y y

End time of period 1: h h m m (24 hr) *Time patient was transferred to ICU/ITU + 23:59 hrs*

Holter monitor ID number | | | | | | - | | | | | |

Has Holter been changed or removed? Yes, changed ☐ Yes, removed ☐ No ☐

If yes, give reason: _____

If yes, date d d m m y y y y

Time h h m m (24hrs)

If Holter has been changed: replacement Holter monitor ID number | | | | | | - | | | | | |

Renal replacement therapy post surgery Yes ☐ No ☐

Period 1 (0-24Hrs)

Tight K Patient ID: | T | K | | | | | | ***Initials:*** | | | |

Cardiac pacing - wire(s) in place?	Yes	☐	No	☐
If yes, is pacing box switched on?	Yes	☐	No	☐
Resternotomy	Yes	☐	No	☐
Cardioversion-DC	Yes	☐	No	☐
Cardioversion-Chemical	Yes	☐	No	☐
Take-back to surgery?	Yes	☐	No	☐

If yes, give reason: _____

Period 1 (0-24Hrs)

Tight K Patient ID: T K

Initials:

Has the patient experienced AFACS (Atrial Fibrillation After Cardiac Surgery: defined as any of atrial fibrillation, atrial flutter or atrial tachycardia)? Yes ☐ No ☐

Was AFACS ≥30 seconds? Yes ☐ No ☐

If yes, was this electrocardiographically confirmed (by either electrocardiogram (ECG), telemetry, or defibrillator monitor)?: Yes ☐ No ☐

If yes, have you stored a copy of the ECG, and/or rhythm strip/telemetry printout? Yes ☐ No ☐

Start date & time (of AFACS) d d m m y y y y h h m m (24hrs)

Is assessment of duration possible? Yes ☐ No ☐

If yes, duration s s s s (seconds)

Was onset of AFACS within 30 minutes of inserting or manipulating (re-dressing, re-wiring, re-stitching etc) a central venous neckline? Yes ☐ No ☐ Not known ☐

Has the patient experienced second AFACS? Yes ☐ No ☐

*In eCRF **click** to add new event details as required*

Were any of the following rhythms present during this period:	**YES**	**NO**	**NOT KNOWN**
Sinus rhythm			
Non-AF supraventricular tachycardia (≥30 seconds)			
Ventricular tachycardia/fibrillation (more than 3 beats at >100 bpm)			
Mobitz type 2 block			
Complete heart block			
Other ventricular pause of ≥3 seconds (if not described above)			
Junctional rhythm			

Period 1 (0-24Hrs)

Tight K Patient ID: | T | K | | | | | |

Initials: | | | |

Potassium measurements

Date (dd/mm/yyyy)	Time (hh:mm)				Indicate Blood Gas (B), Lab (L) or Point of Care (P)	Value (mmol/L)	Potassium given? Yes (Y) or No (N)	If yes, confirm type given: IV, oral, food or nasogastric feeding	Was a red blood cell blood transfusion given? (Y) or (N)
__ __/__ __/__ __ __ __	h	h	m	m					
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__ __/__ __/__ __ __ __	h	h	m	m					

*In eCRF **click** to add new line as required*

Period 1 (0-24Hrs)

Tight K Patient ID: | T | K | | | | | |

Initials: | | | |

Were any potassium lowering or sparing agents given during this period? Yes ☐ No ☐

If yes, please indicate what was given?

Potassium lowering agents (IV) Yes ☐ No ☐

Potassium lowering agents (nebuliser) Yes ☐ No ☐

Potassium lowering agents (oral medication) Yes ☐ No ☐

Potassium sparing agents (oral medication) Yes ☐ No ☐

β-Blockers prescribed this period? Yes ☐ No ☐

Amiodarone prescribed this period? Yes ☐ No ☐

Magnesium prescribed this period? Yes ☐ No ☐

Digoxin prescribed this period? Yes ☐ No ☐

Vernakalant prescribed this period? Yes ☐ No ☐

Steroids prescribed this period? Yes ☐ No ☐

C-Reactive Protein	Collected? YES	NO	If yes, time	Value	
CRP					mg/L

Is the patient alive at the end of period 1? Yes ☐ No ☐ *If No, please complete a Cause of Death form (page 53)*

Is the patient still in hospital at the end of period 1? Yes ☐ No ☐

Period 2 (24-48Hrs)

Tight K Patient ID: T K | | | | | |

Initials: | | |

Start date Period 2: d d m m y y y y

Start time of period 2: h h m m (24 hr) *End time of period 1 + 00:01 hrs*

End date Period 2: d d m m y y y y

End time of period 2: h h m m (24 hr) *Start time of period 2 + 23:59 hrs*

Holter monitor ID number | | | | | | - | | | | |

Has Holter been changed or removed? Yes, changed ☐ Yes, removed ☐ No ☐

If yes, give reason: _____

If yes, date d d m m y y y y

Time h h m m (24hrs)

If Holter has been changed: replacement Holter monitor ID number | | | | | | - | | | | |

Renal replacement therapy post surgery Yes ☐ No ☐

Period 2 (24-48Hrs)

Tight K Patient ID: | T | K | | | | | | ***Initials:*** | | | |

Cardiac pacing - wire(s) in place?	Yes	☐	No	☐
If yes, is pacing box switched on?	Yes	☐	No	☐
Resternotomy	Yes	☐	No	☐
Cardioversion-DC	Yes	☐	No	☐
Cardioversion-Chemical	Yes	☐	No	☐
Take-back to surgery?	Yes	☐	No	☐

If yes, give reason: _____

Period 2 (24-48Hrs)

Tight K Patient ID: T K

Initials:

Has the patient experienced AFACS (Atrial Fibrillation After Cardiac Surgery: defined as any of atrial fibrillation, atrial flutter or atrial tachycardia)? Yes ☐ No ☐

Was AFACS ≥30 seconds? Yes ☐ No ☐

If yes, was this electrocardiographically confirmed (by either electrocardiogram (ECG), telemetry, or defibrillator monitor)?: Yes ☐ No ☐

If yes, have you stored a copy of the ECG, and/or rhythm strip/telemetry printout? Yes ☐ No ☐

Start date & time (of AFACS) d d m m y y y y h h m m (24hrs)

Is assessment of duration possible? Yes ☐ No ☐

If yes, duration s s s s (seconds)

Was onset of AFACS within 30 minutes of inserting or manipulating (re-dressing, re-wiring, re-stitching etc) a central venous neckline? Yes ☐ No ☐ Not known ☐

Has the patient experienced second AFACS? Yes ☐ No ☐

*In eCRF **click** to add new event details as required*

Were any of the following rhythms present during this period:	**YES**	**NO**	**NOT KNOWN**
Sinus rhythm			
Non-AF supraventricular tachycardia (≥30 seconds)			
Ventricular tachycardia/fibrillation (more than 3 beats at >100 bpm)			
Mobitz type 2 block			
Complete heart block			
Other ventricular pause of ≥3 seconds (if not described above)			
Junctional rhythm			

Period 2 (24-48Hrs)

Tight K Patient ID:

T	K					

Initials:

Potassium measurements

Date (dd/mm/yyyy)	Time (hh:mm)				Indicate Blood Gas (B), Lab (L) or Point of Care (P)	Value (mmol/L)	Potassium given? Yes (Y) or No (N)	If yes, confirm type given: IV, oral, food or nasogastric feeding	Was a red blood cell blood transfusion given? (Y) or (N)
__ __/__ __/__ __ __ __	h	h	m	m					
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__ __/__ __/__ __ __ __	h	h	m	m					

*In eCRF **click** to add new line as required*

Period 2 (24-48Hrs)

Tight K Patient ID: | T | K | | | | | |

Initials: | | | |

Were any potassium lowering or sparing agents given during this period? Yes ☐ No ☐

If yes, please indicate what was given?

Potassium lowering agents (IV) Yes ☐ No ☐

Potassium lowering agents (nebuliser) Yes ☐ No ☐

Potassium lowering agents (oral medication) Yes ☐ No ☐

Potassium sparing agents (oral medication) Yes ☐ No ☐

β-Blockers prescribed this period? Yes ☐ No ☐

Amiodarone prescribed this period? Yes ☐ No ☐

Magnesium prescribed this period? Yes ☐ No ☐

Digoxin prescribed this period? Yes ☐ No ☐

Vernakalant prescribed this period? Yes ☐ No ☐

Steroids prescribed this period? Yes ☐ No ☐

C-Reactive Protein	Collected? YES	NO	If yes, time	Value	
CRP					mg/L

Is the patient alive at the end of period 2? Yes ☐ No ☐ *If No, please complete a Cause of Death form (page 53)*

Is the patient still in hospital at the end of period 2? Yes ☐ No ☐

Period 3 (48-72Hrs)

Tight K Patient ID: T K | | | | | | |

Initials: | | |

Start date Period 3: d d m m y y y y

Start time of period 3: h h m m (24 hr) *End time of period 2 + 00:01 hrs*

End date Period 3: d d m m y y y y

End time of period 3: h h m m (24 hr) *Start time of Period 3 + 23:59 hrs*

Holter monitor ID number | | | | | | - | | | | |

Has Holter been changed or removed? Yes, changed ☐ Yes, removed ☐ No ☐

If yes, give reason: _____

If yes, date d d m m y y y y

Time h h m m (24hrs)

If Holter has been changed: replacement Holter monitor ID number | | | | | | - | | | | |

Renal replacement therapy post surgery Yes ☐ No ☐

Period 3 (48-72Hrs)

Tight K Patient ID: | T | K | | | | | | ***Initials:*** | | | |

Cardiac pacing - wire(s) in place? Yes ☐ No ☐

If yes, is pacing box switched on? Yes ☐ No ☐

Resternotomy Yes ☐ No ☐

Cardioversion-DC Yes ☐ No ☐

Cardioversion-Chemical Yes ☐ No ☐

Take-back to surgery? Yes ☐ No ☐

If yes, give reason: _____

Period 3 (48-72Hrs)

Tight K Patient ID: T K

Initials:

Has the patient experienced AFACS (Atrial Fibrillation After Cardiac Surgery: defined as any of atrial fibrillation, atrial flutter or atrial tachycardia)? Yes ☐ No ☐

Was AFACS ≥30 seconds? Yes ☐ No ☐

If yes, was this electrocardiographically confirmed (by either electrocardiogram (ECG), telemetry, or defibrillator monitor)?: Yes ☐ No ☐

If yes, have you stored a copy of the ECG, and/or rhythm strip/telemetry printout? Yes ☐ No ☐

Start date & time (of AFACS) d d m m y y y y h h m m (24hrs)

Is assessment of duration possible? Yes ☐ No ☐

If yes, duration s s s s (seconds)

Was onset of AFACS within 30 minutes of inserting or manipulating (re-dressing, re-wiring, re-stitching etc) a central venous neckline? Yes ☐ No ☐ Not known ☐

Has the patient experienced second AFACS? Yes ☐ No ☐

*In eCRF **click** to add new event details as required*

Were any of the following rhythms present during this period:	**YES**	**NO**	**NOT KNOWN**
Sinus rhythm			
Non-AF supraventricular tachycardia (≥30 seconds)			
Ventricular tachycardia/fibrillation (more than 3 beats at >100 bpm)			
Mobitz type 2 block			
Complete heart block			
Other ventricular pause of ≥3 seconds (if not described above)			
Junctional rhythm			

Period 3 (48-72Hrs)

Tight K Patient ID:

T	K					

Initials:

Potassium measurements

Date (dd/mm/yyyy)	Time (hh:mm)				Indicate Blood Gas (B), Lab (L) or Point of Care (P)	Value (mmol/L)	Potassium given? Yes (Y) or No (N)	If yes, confirm type given: IV, oral, food or nasogastric feeding	Was a red blood cell blood transfusion given? (Y) or (N)
__ __/__ __/__ __ __ __	h	h	m	m					
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*In eCRF **click** to add new line as required*

Period 3 (48-72Hrs)

Tight K Patient ID: | T | K | | | | | |

Initials: | | | |

Were any potassium lowering or sparing agents given during this period? Yes ☐ No ☐

If yes, please indicate what was given?

Potassium lowering agents (IV) Yes ☐ No ☐

Potassium lowering agents (nebuliser) Yes ☐ No ☐

Potassium lowering agents (oral medication) Yes ☐ No ☐

Potassium sparing agents (oral medication) Yes ☐ No ☐

β-Blockers prescribed this period? Yes ☐ No ☐

Amiodarone prescribed this period? Yes ☐ No ☐

Magnesium prescribed this period? Yes ☐ No ☐

Digoxin prescribed this period? Yes ☐ No ☐

Vernakalant prescribed this period? Yes ☐ No ☐

Steroids prescribed this period? Yes ☐ No ☐

C-Reactive Protein	Collected? YES	NO	If yes, time	Value	
CRP					mg/L

Is the patient alive at the end of period 3? Yes ☐ No ☐ *If No, please complete a Cause of Death form (page 53)*

Is the patient still in hospital at the end of period 3? Yes ☐ No ☐

Period 4 (72-96Hrs)

Tight K Patient ID: T K | | | | | |

Initials: | | |

Start date Period 4: d d m m y y y y

Start time of period 4: h h m m (24 hr) *End time of period 3 + 00:01 hrs*

End date Period 4: d d m m y y y y

End time of period 4: h h m m (24 hr) *Start time of Period 4 + 23:59 hrs*

Holter monitor ID number | | | | | | - | | | | |

Has Holter been changed or removed? Yes, changed ☐ Yes, removed ☐ No ☐

If yes, give reason: _____

If yes, date d d m m y y y y

Time h h m m (24hrs)

If Holter has been changed: replacement Holter monitor ID number | | | | | | - | | | | |

Renal replacement therapy post surgery Yes ☐ No ☐

Period 4 (72-96Hrs)

Tight K Patient ID: T K | | | | | |

Initials: | | |

Cardiac pacing - wire(s) in place? Yes ☐ No ☐

If yes, is pacing box switched on? Yes ☐ No ☐

Resternotomy Yes ☐ No ☐

Cardioversion-DC Yes ☐ No ☐

Cardioversion-Chemical Yes ☐ No ☐

Take-back to surgery? Yes ☐ No ☐

If yes, give reason: _____

Period 4 (72-96Hrs)

Tight K Patient ID: T K

Initials:

Has the patient experienced AFACS (Atrial Fibrillation After Cardiac Surgery: defined as any of atrial fibrillation, atrial flutter or atrial tachycardia)? Yes ☐ No ☐

Was AFACS ≥30 seconds? Yes ☐ No ☐

If yes, was this electrocardiographically confirmed (by either electrocardiogram (ECG), telemetry, or defibrillator monitor)?: Yes ☐ No ☐

If yes, have you stored a copy of the ECG, and/or rhythm strip/telemetry printout? Yes ☐ No ☐

Start date & time (of AFACS) d d m m y y y y h h m m (24hrs)

Is assessment of duration possible? Yes ☐ No ☐

If yes, duration s s s s (seconds)

Was onset of AFACS within 30 minutes of inserting or manipulating (re-dressing, re-wiring, re-stitching etc) a central venous neckline? Yes ☐ No ☐ Not known ☐

Has the patient experienced second AFACS? Yes ☐ No ☐

*In eCRF **click** to add new event details as required*

Were any of the following rhythms present during this period:	**YES**	**NO**	**NOT KNOWN**
Sinus rhythm			
Non-AF supraventricular tachycardia (≥30 seconds)			
Ventricular tachycardia/fibrillation (more than 3 beats at >100 bpm)			
Mobitz type 2 block			
Complete heart block			
Other ventricular pause of ≥3 seconds (if not described above)			
Junctional rhythm			

Period 4 (72-96Hrs)

Tight K Patient ID: | T | K | | | | | | ***Initials:*** | | | |

Potassium measurements

Date (dd/mm/yyyy)	Time (hh:mm)				Indicate Blood Gas (B), Lab (L) or Point of Care (P)	Value (mmol/L)	Potassium given? Yes (Y) or No (N)	If yes, confirm type given: IV, oral, food or nasogastric feeding	Was a red blood cell blood transfusion given? (Y) or (N)
__ __/__ __/__ __ __ __	h	h	m	m					
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*In eCRF **click** to add new line as required*

Period 4 (72-96Hrs)

Tight K Patient ID: | T | K | | | | | |

Initials: | | | |

Were any potassium lowering or sparing agents given during this period? Yes ☐ No ☐

If yes, please indicate what was given?

Potassium lowering agents (IV) Yes ☐ No ☐

Potassium lowering agents (nebuliser) Yes ☐ No ☐

Potassium lowering agents (oral medication) Yes ☐ No ☐

Potassium sparing agents (oral medication) Yes ☐ No ☐

β-Blockers prescribed this period? Yes ☐ No ☐

Amiodarone prescribed this period? Yes ☐ No ☐

Magnesium prescribed this period? Yes ☐ No ☐

Digoxin prescribed this period? Yes ☐ No ☐

Vernakalant prescribed this period? Yes ☐ No ☐

Steroids prescribed this period? Yes ☐ No ☐

C-Reactive Protein	Collected? YES	NO	If yes, time	Value	
CRP					mg/L

Is the patient alive at the end of period 4? Yes ☐ No ☐ *If No, please complete a Cause of Death form (page 53)*

Is the patient still in hospital at the end of period 4? Yes ☐ No ☐

Period 5 (96-120Hrs)

Tight K Patient ID: T K | | | | | |

Initials: | | |

Start date Period 5: d d m m y y y y

Start time of period 5: h h m m (24 hr) *End time of period 4 + 00:01 hrs*

End date Period 5: d d m m y y y y

End time of period 5: h h m m (24 hr) *Start time of Period 5 + 23:59 hrs*

Holter monitor ID number | | | | | | - | | | | |

Has Holter been changed or removed? Yes, changed ☐ Yes, removed ☐ No ☐

If yes, give reason: _____

If yes, date d d m m y y y y

Time h h m m (24hrs)

If Holter has been changed: replacement Holter monitor ID number | | | | | | - | | | | |

Renal replacement therapy post surgery Yes ☐ No ☐

Period 5 (96-120Hrs)

Tight K Patient ID: | T | K | | | | | | ***Initials:*** | | | |

Cardiac pacing - wire(s) in place? Yes ☐ No ☐

If yes, is pacing box switched on? Yes ☐ No ☐

Resternotomy Yes ☐ No ☐

Cardioversion-DC Yes ☐ No ☐

Cardioversion-Chemical Yes ☐ No ☐

Take-back to surgery? Yes ☐ No ☐

If yes, give reason: _____

Period 5 (96-120Hrs)

Tight K Patient ID: T K

Initials:

Has the patient experienced AFACS (Atrial Fibrillation After Cardiac Surgery: defined as any of atrial fibrillation, atrial flutter or atrial tachycardia)? Yes ☐ No ☐

Was AFACS ≥30 seconds? Yes ☐ No ☐

If yes, was this electrocardiographically confirmed (by either electrocardiogram (ECG), telemetry, or defibrillator monitor)?: Yes ☐ No ☐

If yes, have you stored a copy of the ECG, and/or rhythm strip/telemetry printout? Yes ☐ No ☐

Start date & time (of AFACS) d d m m y y y y h h m m (24hrs)

Is assessment of duration possible? Yes ☐ No ☐

If yes, duration s s s s (seconds)

Was onset of AFACS within 30 minutes of inserting or manipulating (re-dressing, re-wiring, re-stitching etc) a central venous neckline? Yes ☐ No ☐ Not known ☐

Has the patient experienced second AFACS? Yes ☐ No ☐

*In eCRF **click** to add new event details as required*

Were any of the following rhythms present during this period:	**YES**	**NO**	**NOT KNOWN**
Sinus rhythm			
Non-AF supraventricular tachycardia (≥30 seconds)			
Ventricular tachycardia/fibrillation (more than 3 beats at >100 bpm)			
Mobitz type 2 block			
Complete heart block			
Other ventricular pause of ≥3 seconds (if not described above)			
Junctional rhythm			

Period 5 (96-120Hrs)

Tight K Patient ID: ***Initials:***

T	K								

Potassium measurements

Date (dd/mm/yyyy)	Time (hh:mm)				Indicate Blood Gas (B), Lab (L) or Point of Care (P)	Value (mmol/L)	Potassium given? Yes (Y) or No (N)	If yes, confirm type given: IV, oral, food or nasogastric feeding	Was a red blood cell blood transfusion given? (Y) or (N)
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*In eCRF **click** to add new line as required*

Period 5 (96-120Hrs)

Tight K Patient ID: | T | K | | | | | | ***Initials:*** | | | |

Were any potassium lowering or sparing agents given during this period? Yes ☐ No ☐

If yes, please indicate what was given?

Potassium lowering agents (IV) Yes ☐ No ☐

Potassium lowering agents (nebuliser) Yes ☐ No ☐

Potassium lowering agents (oral medication) Yes ☐ No ☐

Potassium sparing agents (oral medication) Yes ☐ No ☐

β-Blockers prescribed this period? Yes ☐ No ☐

Amiodarone prescribed this period? Yes ☐ No ☐

Magnesium prescribed this period? Yes ☐ No ☐

Digoxin prescribed this period? Yes ☐ No ☐

Vernakalant prescribed this period? Yes ☐ No ☐

Steroids prescribed this period? Yes ☐ No ☐

C-Reactive Protein	Collected? YES	NO	If yes, time	Value	
CRP					mg/L

Status end period 5

Tight K Patient ID: | T | K | | | | | | ***Initials:*** | | | |

Is the patient alive? Yes ☐ No ☐ *If No, please complete a Cause of Death form (page 53)*

Location of patient at end of period 5: Date d d m m y y y y

ITU/ICU ☐

CCU ☐

Ward ☐

Surgery ☐

Another hospital/hospice ☐

Home ☐

Lost to follow up ☐

Other ☐ _____

Has the holter monitor been sent to the core lab? Yes ☐ No ☐

If no, give reason: _____

Status end period 5 (central venous access)

Tight K Patient ID:

T	K					

Initials:

During periods 1-5 did the patient have central venous access? Yes ☐ No ☐

If Yes:

What date was this inserted?	d	d	m	m	y	y	y	y	
And, if known, what time was this inserted?	h	h	m	m	(24 hr)				
Was the central venous access removed during periods 1-5?	Yes ☐				No ☐				
If YES: What date was this removed?	d	d	m	m	y	y	y	y	
And, if known, what time was this removed?	h	h	m	m	(24 hr)				

Was central venous access reinserted during periods 1-5? Yes ☐ No ☐

If Yes:

What date was this inserted?	d	d	m	m	y	y	y	y	
And, if known, what time was this inserted?	h	h	m	m	(24 hr)				
Was the central venous access removed during periods 1-5?	Yes ☐				No ☐				
If YES: What date was this removed?	d	d	m	m	y	y	y	y	
And, if known, what time was this removed?	h	h	m	m	(24 hr)				

Was central venous access reinserted again during periods 1-5? Yes ☐ No ☐

If Yes:

What date was this inserted?	d	d	m	m	y	y	y	y	
And, if known, what time was this inserted?	h	h	m	m	(24 hr)				
Was the central venous access removed during periods 1-5?	Yes ☐				No ☐				
If YES: What date was this removed?	d	d	m	m	y	y	y	y	
And, if known, what time was this removed?	h	h	m	m	(24 hr)				

Discharge from this hospital

Tight K Patient ID: T K | | | | | | |

Initials: | | |

Is the patient alive? Yes ☐ No ☐ *If No, please complete a Cause of Death form (page 53)*

If Yes, date of discharge d d m m y y y y

If Yes, where discharged to: Home ☐ Another hospital ☐ Care facility ☐

Other ☐ If Other, specify _____

Stroke during the index hospitalisation Yes ☐ No ☐ *If Yes, please complete a stroke form (page 52)*

Heart rate _____ bpm

Pulse regular Yes ☐ No ☐

Between end of period 5 and discharge has the patient experienced AFACS? Yes ☐ No ☐

Were any of the following rhythms present (between end period 5 and discharge):	**YES**	**NO**	**NOT KNOWN**
Sinus rhythm			
Non-AF supraventricular tachycardia (≥30 seconds)			
Ventricular tachycardia/fibrillation (more than 3 beats at >100 bpm)			
Mobitz type 2 block			
Complete heart block			
Other ventricular pause of ≥3 seconds (if not described above)			
Junctional rhythm			

During this admission, has the patient received a permanent pacemaker/defibrillator Yes ☐ No ☐ Not Known ☐

If Yes, please confirm details: _____

Discharge from this hospital

Tight K Patient ID: | T | K | | | | | | | ***Initials:*** | | | |

Have any UNEXPECTED* adverse events occurred since surgery? Yes ☐ No ☐ *If Yes, please complete an SAE or NSAE form*

Please see the Safety Reporting section of the protocol for a list of expected adverse events that **do not need to be reported.*
__Pre-existing conditions__ that are unchanged after the trial treatment period should **not be reported as an SAE/NSAE.*

Expected Adverse Events (from randomisation till discharge)	**NO**	**YES**	**If yes, no. of events**
Hyperkalaemia (K+ ≥ 5.5mEq/L)			
Nausea			
Line site complications (phlebitis, infection etc)			
Skin irritation from ECG electrodes			
Stroke			
Prolonged mechanical support			
Post-op delirium			
Transfusion of Blood or Blood Products (RBC, FFP or Platelets)			
Pericarditis			
Ulnar nerve paraesthesia			
Heart block requiring pacemaker			
Intra-aortic balloon pump insertion			
Urinary tract infection			
Suprapubic catheter			
Urinary retention			

This list is continued on the following page

Please <u>do not</u> complete an SAE or NSAE form for any of the expected adverse events listed

Discharge from this hospital

Tight K Patient ID:

T	K					

Initials:

Expected Adverse Events (from randomisation till discharge)	**NO**	**YES**	**If yes, no. of events**
Constipation*			
Vomiting*			
Wound infection (sternum or donor site)*			
Return to theatre for bleeding*			
Heart failure*			
Myocardial infarction*			
Non-cardiac chest pain*			
Pericardial effusion*			
Pleural effusion*			
Chest drain insertion* (excluding intra-operative drains from the index procedure)			
Chest infection (pneumonia)*			
Lung atelectasis*			
Pneumothorax*			
Renal failure requiring dialysis*			
Renal impairment not requiring dialysis*			
Shortness of breath *caused by any of the above**			

Please <u>do not</u> complete an SAE or NSAE form for any of the expected adverse events listed

Medications at Discharge

Tight K Patient ID: | T | K | | | | | |

Initials: | | | |

Antiplatelets	YES	NO	NOT KNOWN
Antiplatelets			

β-Blockers	YES	NO	NOT KNOWN
β-Blockers			

ACE Inhibitors	YES	NO	NOT KNOWN
ACE Inhibitors			

Angiotensin Receptor Blockers	YES	NO	NOT KNOWN
Angiotensin Receptor Blockers			

Calcium Channel Blockers	YES	NO	NOT KNOWN
Calcium Channel Blockers			

Digoxin	YES	NO	NOT KNOWN
Digoxin			

Anti-Diabetic Drugs	YES	NO	NOT KNOWN
Insulin			
Non-insulin anti-diabetic drugs (tablets or injections excluding SGLT-2 inhibitors)			
Diet controlled			

SGLT-2 inhibitors	YES	NO	NOT KNOWN
SGLT-2 inhibitors			

f-channel inhibitors	YES	NO	NOT KNOWN
f-channel inhibitors			

Medications at Discharge

Tight K Patient ID: | T | K | | | | | |

Initials: | | | |

Oral Anticoagulants	YES	NO	NOT KNOWN
NOACs/DOAC's (*not* NSAIDS)			
If yes, NOAC/DOAC, was it prescribed specifically because of atrial fibrillation, atrial flutter or atrial tachycardia?			
Warfarin			
If yes, Warfarin, was it prescribed specifically because of atrial fibrillation, atrial flutter or atrial tachycardia?			

Diuretics	YES	NO	NOT KNOWN	
Thiazide Diuretics				
Aldosterone Antagonist				
Loop Diuretics				
Other (If Yes, specify)				

Antianginal Drugs	YES	NO	NOT KNOWN
Antianginal drugs			

Amiodarone	YES	NO	NOT KNOWN
Amiodarone			
If yes, was it prescribed specifically because of atrial fibrillation, atrial flutter or atrial tachycardia?			

Potassium supplements	YES	NO	NOT KNOWN
Potassium supplements			

Statins	YES	NO	NOT KNOWN
Statins			

Patient hospital stay at Discharge

Tight K Patient ID:

T	K					

Initials:

Hospital stay following postoperative admission to ICU

Location	Total stay in days
ITU/ICU	
CCU	
Ward	
Fast track unit	
Other (specify below)	

***Please note:** if your site records hospital stay in hours, then please enter the stay in days to one decimal place (e.g. 1 day 5 hours = 1.2 days)*

Follow up 6 months

Tight K Patient ID: | T | K | | | | | | ***Initials:*** | | | |

Is the patient alive? Yes ☐ No ☐ *If No, please complete a Cause of Death form (page 53)*

If Yes, date of interview/data collection? d d m m y y y y

Location of patient at 6 months

- Home ☐
- In hospital ☐
- Care facility ☐
- Lost to follow up ☐
- Other ☐ _____

Since discharge has the patient experienced AFACS? Yes ☐ No ☐

If yes, start date & time d d m m y y y y h h m m (24hrs)

Were any of the following rhythms present (between discharge and 6 month follow up):	**YES**	**NO**	**NOT KNOWN**
Sinus rhythm			
Non-AF supraventricular tachycardia (≥30 seconds)			
Ventricular tachycardia/fibrillation (more than 3 beats at >100 bpm)			
Mobitz type 2 block			
Complete heart block			
Other ventricular pause of ≥3 seconds (if not described above)			
Junctional rhythm			

Since discharge, has the patient received a permanent pacemaker/defibrillator Yes ☐ No ☐ Not Known ☐

If Yes, please confirm details: _____

Follow up 6 months

Tight K Patient ID:

T	K					

Initials:

Since discharge, has the patient commenced treatment with anticoagulants?

	YES	NO	NOT KNOWN
Warfarin			
DOAC			

If yes to either question above, why was anticoagulation therapy commenced? (select all that apply):

Atrial fibrillation since cardiac surgery — Yes ☐ No ☐

If yes, is the AF: (select one)

- Single episode ☐
- Paroxysmal AF (intermittent and recurring) ☐
- Persistent ☐

Treatment of DVT/PE — Yes ☐ No ☐

LV Thrombus — Yes ☐ No ☐

Other — Yes ☐ No ☐

Specify other: _____

Follow up 6 months

Tight K Patient ID: ***Initials:***

T	K								

Have any UNEXPECTED* adverse events occurred since discharge? Yes ☐ No ☐ *If Yes, please complete an SAE or NSAE form*

Please see the Safety Reporting section of the protocol for a list of expected adverse events that **do not need to be reported.*
__Pre-existing conditions__ that are unchanged after the trial treatment period should **not be reported as an SAE/NSAE.*

Expected Adverse Events (from discharge till 6 months)	**NO**	**YES**	**If yes, no. of events**
Hyperkalaemia (K+ ≥ 5.5mEq/L)			
Nausea			
Line site complications (phlebitis, infection etc)			
Skin irritation from ECG electrodes			
Stroke *(if yes, please complete a stroke form, page 52)*			
Prolonged mechanical support			
Post-op delirium			
Transfusion of Blood or Blood Products (RBC, FFP or Platelets)			
Pericarditis			
Ulnar nerve paraesthesia			
Heart block requiring pacemaker			
Intra-aortic balloon pump insertion			
Urinary tract infection			
Suprapubic catheter			
Urinary retention			

This list is continued on the following page

Please do not complete an SAE or NSAE form for any of the expected adverse events listed

Follow up 6 months

Tight K Patient ID:

T	K					

Initials:

Expected Adverse Events (from discharge till 6 months)	**NO**	**YES**	**If yes, no. of events**
Constipation*			
Vomiting*			
Wound infection (sternum or donor site)*			
Return to theatre for bleeding*			
Heart failure*			
Myocardial infarction*			
Non-cardiac chest pain*			
Pericardial effusion*			
Pleural effusion*			
Chest drain insertion*			
Chest infection (pneumonia)*			
Lung atelectasis*			
Pneumothorax*			
Renal failure requiring dialysis*			
Renal impairment not requiring dialysis*			
Shortness of breath *caused by any of the above**			

Please <u>do not</u> complete an SAE or NSAE form for any of the expected adverse events listed

Does the patient have any recollection of receiving potassium supplementation, during their admission for CABG surgery

Yes ☐ No ☐

Has the Patient completed the EQ-5D-5L?

Yes ☐ No ☐

Stroke Form

Tight K Patient ID: | T | K | | | | | |

Initials: | | | |

Date of stroke | d | d | m | m | y | y | y | y |

Hospital name _____

Clinical features:

_____

_____

_____

Brain imaging CT ☐ MRI ☐ None ☐

Result: _____

Stroke diagnosis Ischaemic ☐ Haemorrhagic ☐ Possible stroke ☐

Was stroke diagnosed during the index hospitalisation? Yes ☐ No ☐

Other relevant information:

_____

_____

_____

Cause of Death Form

Tight K Patient ID: ***Initials:***

T	K								

Date of death: d d m m y y y y

Detailed description of cause of death *(from death certificate or relevant medical notes)*:

Was the primary cause of death:

01: Heart failure ☐ **02:** Acute MI ☐ **03:** Other cardiovascular death ☐

04: Hyperkalaemia ☐ **05:** Hypokalaemia ☐ **06:** Other non cardiovascular death ☐

07: Unknown * ☐ (* in the absence of an identifiable cause of death)

Autopsy information available? Yes ☐ No ☐

If Yes, provide details: