



**Corticosteroid Randomisation
After Significant Head Injury**

A LARGE SIMPLE PLACEBO CONTROLLED TRIAL, AMONG ADULTS WITH HEAD INJURY AND IMPAIRED CONSCIOUSNESS,
OF THE EFFECTS OF A 48-HOUR INFUSION OF CORTICOSTEROIDS ON DEATH AND NEUROLOGICAL DISABILITY

DATA DICTIONARY FOR
THE DATA SET CRASH
DATA (CRASH data.csv)

EXCLUDED FROM THE CRASH DATA SET ARE THE VARIABLES:

Country, hospital code and intervention

**THESE VARIABLES MAY BE REQUESTED FROM THE CTU. A SUMMARY PROTOCOL DETAILING THE
USE THAT WILL BE MADE OF THIS DATA MUST BE PROVIDED WITH THE REQUEST.**

DATA DEFINITION FILE FOR CRASH DATASET: CRASH data.csv (Excel comma separated value file)					
Variable	Label	Comments	Maximum Length	Type	Codes
BASELINE DATA					
Patient ID	Six digit unique identifier for each patient	Derived from the treatment box-pack number	7	String	
SEX	Gender of the patient		1	Number	0 = Male 1 = Female
AGE	Estimated age in years if DOB not known		2	Number	-1 = DOB known and entered
DRAND	Date of randomisation	DD/MM/YYYY	10	Date	
TRAND	Time of randomisation	HH:MM:SS	8	Time	
MINS_SINCE_INJURY	Number of minutes since injury		4	Number	
GCS_EYE	Glasgow Coma Scale: Eye opening		1	Number	4 = Spontaneous 3 = To sound 2 = To pain 1 = None
GCS_MOTOR	Glasgow Coma Scale: Motor response		1	Number	6 = Obeys commands 5 = Localising 4 = Normal flexion 3 = Abnormal flexion 2 = Extending 1 = None
GCS_VERBAL	Glasgow Coma Scale: Verbal response		1	Number	5 = Orientated 4 = Confused speech 3 = Words 2 = Sounds 1 = None

Variable	Label	Comments	Maximum Length	Type	Codes
IS_GCS_CURRENT	Indicates whether GCS is current or most recent		1	Number	1 = Current 2 = Most recent
PUPIL_REACT_LEFT	Pupil reactivity left eye		1	Number	1 = Yes 2 = No 3 = Unable to assess
PUPIL_REACT_RIGHT	Pupil reactivity right eye		1	Number	1 = Yes 2 = No 3 = Unable to assess
EARLY OUTCOME DATA – within two weeks from randomisation – FORM COMPLETED AT ADMITTING HOSPITAL [EO= early outcome form]					
EO_Cause	Cause of injury		1	Number	1 = Road Traffic Accident 2 = Fall >2 metres 3 = Other
EO_Cause specified	Description of other cause of injury		68	String	Free text
EO_Outcome	Dead or alive within two weeks after injury		1	Number	1 = Death in hospital 2 = Transferred to other acute care hospital 3 = Discharged to rehabilitation centre or nursing home 4 = Discharged home 5 = Still in this hospital now
EO_Date of outcome	Date of outcome		10	Date	

Variable	Label	Comments	Maximum Length	Type	Codes
EO_Symptoms	Condition of patient at early outcome		1	Number	1 = No symptoms 2 = Minor symptoms 3 = Some restriction in lifestyle but independent 4 = Dependent, but not requiring constant attention 5 = Fully dependent, requiring attention day and night 6 = Dead 9 = Known to be alive at 6M but symptoms not known at day 14
EO_Days ICU	Number of days spent in Intensive Care Unit		2	Number	
EO_Seizure	Seizure Yes or No		1	Number	1 = Yes 2 = No
EO_Haematemesis or melaena	Haematemesis or melaena requiring transfusion Yes or No		1	Number	1 = Yes 2 = No
EO_Wound infection	Wound infection with pus Yes or No		1	Number	1 = Yes 2 = No
EO_Pneumonia TWAB	Pneumonia treated with antibiotics Yes or No		1	Number	1 = Yes 2 = No
EO_Other TWAB	Other treated with antibiotics Yes or No		1	Number	1 = Yes 2 = No
EO_Neurosurgical	Neurosurgical operation Yes or No		1	Number	1 = Yes 2 = No
EO_Major EC injury	Major extracranial injury Yes or No		1	Number	1 = Yes 2 = No

Variable	Label	Comments	Maximum Length	Type	Codes
EO_Head CT scan	Head CT scan done Yes or No		1	Number	1 = Yes 2 = No
EO_Date of CT	Date and time of CT scan	DD/MM/YYYY HH:MM:SS	10	Date and time	
EO_Normal scan	Normal scan Yes or No		1	Number	1 = Yes 2 = No
EO_1 or more PH	1 or more petechial haemorrhages within the brain Yes or No		1	Number	1 = Yes 2 = No
EO_Obliteration 3rdVorBC	Obliteration of the 3 rd ventricle or basal cisterns Yes or No		1	Number	1 = Yes 2 = No
EO_Subarachnoid bleed	Subarachnoid bleed Yes or No		1	Number	1 = Yes 2 = No
EO_Midline shift >5mm	Midline shift >5mm Yes or No		1	Number	1 = Yes 2 = No
EO_Non-evac haem	Intracranial haematoma non-evacuated Yes or No		1	Number	1 = Yes 2 = No
EO_Evac haem	Intracranial haematoma evacuated Yes or No		1	Number	1 = Yes 2 = No
EO>Loading	Loading dose of trial treatment given Yes or No		1	Number	1 = Yes 2 = No
EO>Maintenance	Number of hours of maintenance dose of trial treatment given		2	Number	

EARLY OUTCOME DATA – within two weeks from randomisation – FORM COMPLETED AT HOSPITAL PATIENT WAS TRANSFERRED TO [TH=transfer hospital early outcome form]					
Variable	Label	Comments	Maximum Length	Type	Codes
TH_Cause	Cause of injury		1	Number	1 = Road Traffic Accident 2 = Fall >2 metres 3 = Other
TH_Cause specified	Description of other cause of injury		48	String	Free text
TH_Outcome	Dead or alive at transfer hospital within two weeks after injury		1	Number	1 = Death in hospital 2 = Transferred to other acute care hospital 3 = Discharged to rehabilitation centre or nursing home 4 = Discharged home 5 = Still in this hospital now
TH_Date of outcome	Date of outcome	DD/MM/YYYY	10	Date	
TH_Symptoms	Condition of patient at early outcome		1	Number	1 = No symptoms 2 = Minor symptoms 3 = Some restriction in lifestyle but independent 4 = Dependent, but not requiring constant attention 5 = Fully dependent, requiring attention day and night 6 = Dead 9 = Known to be alive at 6M but symptoms not known at day 14
TH_Days ICU	Number of days spent in Intensive Care Unit		2	Number	

Variable	Label	Comments	Maximum Length	Type	Codes
TH_Seizure	Seizure Yes or No		1		1 = Yes 2 = No
TH_Haem or mel	Haematemesis or melaena requiring transfusion Yes or No		1	Number	1 = Yes 2 = No
TH_Wound infection	Wound infection with pus Yes or No		1	Number	1 = Yes 2 = No
TH_Pneumonia TWAB	Pneumonia treated with antibiotics		1	Number	1 = Yes 2 = No
TH_Other TWAB	Other treated with antibiotics Yes or No		1	Number	1 = Yes 2 = No
TH_Neurosurgical	Neurosurgical operation Yes or No		1	Number	1 = Yes 2 = No
TH_Major EC injury	Major extracranial injury Yes or No		1	Number	1 = Yes 2 = No
TH_Head CT scan	Head CT scan done Yes or No		1	Number	1 = Yes 2 = No
TH_Date of CT	Date of CT scan		10	Date	
TH_Normal scan	Normal scan Yes or No		1	Number	1 = Yes 2 = No
TH_1 or more PH	One or more petechial haemorrhages within the brain Yes or No		1	Number	1 = Yes 2 = No
TH_Obliteration 3rdVorBC	Obliteration of the 3 rd ventricle or basal cisterns		1	Number	1 = Yes 2 = No
TH_Subarachnoid bleed	Subarachnoid bleed Yes or No		1	Number	1 = Yes 2 = No

Variable	Label	Comments	Maximum Length	Type	Codes
TH_Midline shift >5mm	Midline shift >5mm Yes or No		1	Number	1 = Yes 2 = No
TH_Non-evac haem	Intracranial haematoma non-evacuated Yes or No		1	Number	1 = Yes 2 = No
TH_Evac haem	Intracranial haematoma evacuated Yes or No		1	Number	1 = Yes 2 = No
TH>Loading	Loading dose of trial treatment given Yes or No		1	Number	1 = Yes 2 = No
TH>Maintenance	Number of hours maintenance dose of trial treatment given		2	Number	
SIX MONTH OUTCOME (5 level questionnaire)					
6M5_Who	Who completed the questionnaire		1	Number	1 = Patient alone 2 = Relative, friend or carer alone 3 = Patient and relative, friend or carer together
6M5_Living	Where the patient lives		1	Number	1 = In own home 2 = In hospital 3 = In residential care
6M5_Home	Help required in the home		1	Number	1 = No 2 = Yes. I need some help in the home but not every day 3 = Yes. I need help in the home every day 4 = I need help in the home, but not because of the injury

Variable	Label	Comments	Maximum Length	Type	Codes
6M5_Shopping	Help needed to shop		1	Number	1 = No 2 = Yes. I need some help, but can go to the shops on my own 3 = Yes. I need help to shop even locally, or I cannot shop at all 4 = I need help to shop, but not because of the injury
6M5_Travelling	Help needed to travel		1	Number	1 = No 2 = Yes. I need some help but can travel on my own (e.g. by arranging a taxi) 3 = Yes. I need help to travel even locally, or I cannot travel at all 4 = I need help to travel, but not because of the injury
6M5_Working	Any change in ability to work, (or to study if a student; or to look after family)		1	Number	1 = No 2 = Yes. I still work, but at a reduced level (e.g. a change from full-time to part-time, or a change in level of responsibility) 3 = Yes. I am unable to work at present 4 = My ability to work is restricted, but not because of the injury, or I have retired
6M5_Leisure	Change in ability to take part in social and leisure activities outside home		1	Number	1 = No 2 = Yes. I take part a bit less, but at least half as often 3 = Yes. I take part much less, or do not take part at all 4 = My ability to take part is restricted for some other reason, not because of the injury

Variable	Label	Comments	Maximum Length	Type	Codes
6M5_Relationships	Problems in getting on with friends and relatives		1	Number	1 = No 2 = Yes. There are occasional problems (less than once a week) 3 = Yes. There are frequent or constant problems 4 = There are problems for some other reason, not because of the injury
GOS5	Overall assessment		3	String	GR = Good Recovery MD = Moderate Disability SD = Severe Disability SD* = Severe Disability not related to the injury VS = Vegetative State D = Death
SIX MONTH OUTCOME (8 level questionnaire)					
6M8_Who	Who completed the questionnaire		1	Number	1 = Patient alone 2 = Relative, friend or carer alone 3 = Patient and relative, friend or carer together
6M8_Living	Where the patient lives		1	Number	1 = In own home 2 = In hospital 3 = In residential care
6M8_Home Pre-injury	Able to look after oneself at home before the injury		1	Number	1 = Yes 2 = No

Variable	Label	Comments	Maximum Length	Type	Codes
6M8_Home	Help required in the home		1	Number	1 = I do not need help or supervision in the home 2 = I need some help in the home, but not every day 3 = I need help in the home every day, but I could look after myself for at least 8 hours if necessary 4 = I could not look after myself for 8 hours during the day 5 = I need help in the home, but not because of the injury
6M8_Shopping Pre-injury	Help needed to shop before the injury		1	Number	1 = Yes 2 = No
6M8_Shopping	Help needed to shop		1	Number	1 = I do need help to shop 2 = I need some help, but I can go to local shops on my own 3 = I need help to shop even locally, or I cannot shop at all 4 = I need help to shop, but not because of the injury
6M8_Travelling Pre-injury	Help needed to travel before the injury		1	Number	1 = Yes 2 = No
6M8_Travelling	Help needed to travel		1	Number	1 = I do not need help to travel 2 = I need some help, but can travel locally on my own (e.g. by arranging a taxi) 3 = I need help to travel even locally, or I cannot travel at all 4 = I need help to travel but not because of the injury

Variable	Label	Comments	Maximum Length	Type	Codes
6M8_Working Pre-injury	Employment before the injury		1	Number	1 = Working 2 = Looking after the family 3 = Retired 4 = Looking for work 5 = Studying as a student 6 = None of these (e.g. unfit for work)
6M8_Working	Change in ability to work		1	Number	1 = I can still do the same work 2 = I can still work, but at a reduced level (e.g. change from full-time to part-time, or change in level of responsibility) 3 = I am unable to work, or only able to work in sheltered workshop 4 = My ability to work has changed, but not because of the injury
6M8_Leisure Pre-injury	Able to take part in regular social and leisure activities outside the home before the injury	Social and leisure activities include: going out to a pub or club, visiting friends, going to the cinema or bingo, going out for a walk, attending a football match, taking part in sport	1	Number	1 = Yes 2 = No
6M8_Leisure	Able to take part in regular social and leisure activities outside the home		1	Number	1 = I take part about as often as before (the activities may be different from before) 2 = I take part less often, but at least half as often 3 = I take part much less, less than half as often 4 = I do not take part at all 5 = My ability to take part has changed for some other

Variable	Label	Comments	Maximum Length	Type	Codes
6M8_Relationships Pre-injury	Problems getting on with friends or relatives before the injury		1	Number	1 = Yes 2 = No
6M8_Relationships	Problems getting on with friends or relatives		1	Number	1 = Things are still much the same 2 = There are occasional problems (less than once a week) 3 = There are frequent problems (once a week or more) 4 = There are constant problems (problems every day) 5 = There are problems for some other reason, not because of the injury
6M8_Other problems	Any problems resulting from the injury which interfere with daily life	Problems sometimes reported after head injury: headaches, dizziness, tiredness, sensitivity to noise or light, slowness, memory failures, and concentration problems	1	Number	1 = I have no current problems 2 = I have some problems, but these do not interfere with my daily life 3 = I have some problems, but these have affected my daily life 4 = I have some problems for other reasons, not because of the head injury
6M8_Similar problems Pre-injury	Similar problems before the injury		1	Number	1 = I had no problems before, I had minor problems before 2 = I had similar problems before
GOS8			3	String	GR - = lower Good Recovery GR + = upper Good Recovery MD - = lower Moderate Disability MD + = upper Moderate Disability SD - = lower Severe Disability SD + = upper Severe Disability SD* = Severe Disability not related to the injury D = Death

Variable	Label	Comments	Maximum Length	Type	Codes
EO_Tracking code	Lost to follow up		1	Number	11 = Lost to follow up
6M_Tracking code	Status of patient lost to follow up and known to be dead or alive 6 months after injury from source other than 6 month outcome form		1	Number	35 = Lost to follow-up 36 = Known to be dead 38 = Known to be alive