

CONSENT FORM

Tight K ID

Complete after randomisation:

T K

Investigator:

Patient Name:

(Please print full name)

Please *initial*
each box

I confirm that I have read and understand the Tight K Trial Patient Information Sheet (Version 2 dated 01/02/2023). I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and without my medical care or legal rights being affected.

I understand that relevant sections of my medical notes may be looked at by individuals from the Sponsor (Barts Health NHS Trust), the Clinical Trials Unit at the London School of Hygiene & Tropical Medicine, regulatory authorities, and from the NHS Trust, where it is relevant to my taking part in this research.

I understand that data collected during the study may be looked at by individuals from the Sponsor (Barts Health NHS Trust), the Clinical Trials Unit at the London School of Hygiene & Tropical Medicine, Wythenshawe Hospital, regulatory authorities, and from the NHS Trust, where it is relevant to my taking part in this research.

I agree to my General Practitioner being informed about my participation in the study.

I understand that you wish to access my health records held with NHS England and other central UK government bodies that collects outcomes data for linkage, and to do this you will send my NHS number/CHI number and date of birth to these organisations to link to Hospital Episode Statistics (HES), mortality data and cardiovascular outcome data.

I agree for the anonymous information collected about me from this research study to be used to support other health research in the future, and for my anonymised information to be shared with other researchers (NHS, academic and commercial organisations) in the UK and worldwide.

I agree to take part in the study.

Patient signature

Print name

Date and time

Person taking consent signature

Print name

Date and time

When completed: 1 copy for participant, 1 copy for medical notes,
original to be kept in researcher site file


Trial sponsor: **Barts Health**
NHS Trust