

TIGHT K E-BULLETIN



July 2021, Issue 01

OPEN SITES

We are delighted to see sites coming on board and recruiting well almost immediately. We have opened **9** sites, 7 of which have already recruited!

- Blackpool Victoria Hospital
- Castle Hill Hospital
- Hammersmith Hospital
- King's College Hospital
- Leeds General Infirmary
- Liverpool Heart & Chest Hospital -**awaiting green light**
- St Bartholomew's Hospital
- St George's Hospital -**awaiting green light**
- Wythenshawe Hospital



Site	Number randomised
Blackpool Victoria Hospital	3
Castle Hill Hospital	10
Hammersmith Hospital	2
King's College Hospital	9
Leeds General Infirmary	2
St Bartholomew's Hospital	47
Wythenshawe Hospital	7

Table 1: shows the proportion of participants across open sites

RECRUITMENT

Tight K has **80** participants recruited to the study so far. This is a fantastic achievement by our open sites and even puts us very slightly ahead of our recruitment schedule. We would like to encourage any sites not actively engaged in set-up to begin the process soon by contacting us at tightke@LSHTM.ac.uk



@TightKstudy

FAQS



Q: Do we need to do additional potassium level monitoring?

A: No. Sites do not need to change the frequency of monitoring patient's potassium levels. On the wards it is common at many sites to monitor only once a day, and this is fine.

Q: Where do I send Holter monitors to for analysis?

A: Holter monitors are to be sent to the Core Lab at Wythenshawe Hospital in Manchester. Please ensure that you use the pre-paid labels provided, using one label per box. Please do not attach multiple boxes together.

Q: When should we give potassium if the participant is randomised to the the **TIGHT** arm?

A: Potassium is only to be given when levels are **less than 4.5**

Q: When should we give potassium if the participant is randomised to the the **RELAXED** arm?

A: Potassium is only to be given when levels are **less than 3.6**. The only exception is if the participant has a period of AFACS, as defined in the Tight K protocol, after which treatment can return to local standard of care.

Q: Does a high pre-op potassium level automatically exclude a participant from the trial?

A: An isolated high pre-operative potassium level does not necessarily exclude a participant. If there is a suspicion that the result may be inaccurate, either because it is an older measurement or an isolated high reading, it is recommended to repeat the measurement. If the repeated measurement is lower than 5.5 the patient would be eligible to be enrolled.

Q: What about ectopics, as patients seem to do well with potassium?

A: Similar to AF, there is currently no evidence that high potassium levels help with ectopics. Therefore please try to ensure that potassium isn't given outside the protocol for ectopics as this would be considered a protocol violation.

Q: A participant has had a period of AF longer than 1,000 seconds, how do I enter this on the eCRF?

A: Currently there is a validation rule on this field, with an expected range between 30 and 1,000 seconds. We know from experience that sites have recorded genuine instances of periods of AF longer than 1,000 seconds. The way to enter this data is to enter the correct duration length. You will then get a pop up validation box stating the number is too large, but you can just note in the validation box that the figure is correct and then save the form.



CONTACT US

If you have any questions relating to the Tight K trial, please email us at tightk@LSHTM.ac.uk



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