



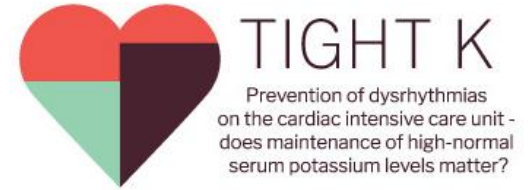
TIGHT K

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

Holter Monitor Training



Organisation



Holter Monitor Supply: **Dot Medical**

Core lab: **Wythenshawe Hospital**

Clinical Trials Unit: **London School of Hygiene and Tropical Medicine**

Main contact at Dot Medical: **Gary Ham**

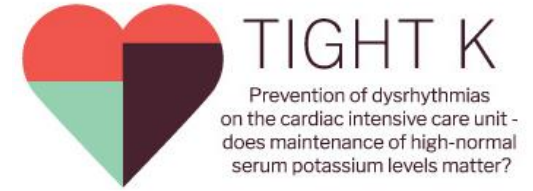
Main contact at core lab: **Keith Pearce**

Trial Manager: **Zahra Jamal** (from August 2021)

Assistant Trial Manager: **Kiran Bal**

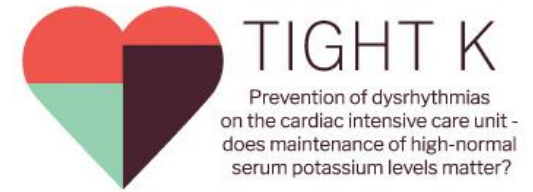
Senior Manager: **Richard Evans**

Background and objectives



- Holter monitors are used to continuously monitor all participant's heart rhythm over the trial treatment period.
- Data from the Holter monitors is used to verify the primary endpoint, and for several secondary endpoints.

Holter information



- We are using the **Bardy DX[®] Carnation Ambulatory Monitor[™]** for Tight K
- This is a small chest-worn monitor.
- It only performs one task - which is to record heart rhythm data from the point it is turned on.
- **No other data is collected or stored on the Holter monitors.**

First supply of Holter monitors



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- You will receive an initial supply of 20 Holter monitors from Dot Medical.
- These will be sent along with an MIA call-off agreement.
 - This confirms indemnity in case of any issues with the Holter monitors.
- The initial supply will usually be after the SIV but can be arranged earlier (for example for Medical Physics to review).
- **You will need to store the Holter monitors appropriately according to the instructions in the packaging material.**

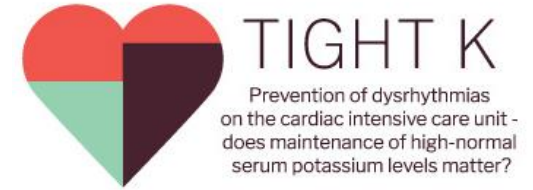
Preparing the patient



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- Ensure the chest area is free from hair.
- If necessary shave the chest with a razor.
- Use the prep pads from the box to clean the area of skin to the left of the sternotomy. The skin should be slightly reddened, but not raw or painful.
- Allow the area to dry thoroughly.

Preparing the Holter Monitors



- Place the electrode on a hard, clean surface.
- Snap the recorder in place by inserting the narrow end into the electrode with the event button facing up (image on left)
- The green light will blink for 10 seconds to confirm activation.
- Press down the event button once to confirm the recorder is in place.

Completing diary card



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- Completing the diary card:
 - Write the **Tight K Study ID** into the patient field
 - Precise **date and time of application** must be recorded
 - Physician field should be left blank
 - Physician and patient phone should be left blank

Carnation Ambulatory Monitor Patient Diary

PATIENT: _____
PHYSICIAN: _____
TIME/DATE APPLIED: _____
TIME/DATE REMOVED: _____
PHYSICIAN PHONE: _____
PATIENT PHONE: _____

Username: MMG1J-EYX33
Password: YQGEF-BBOK9
Obtain your report
www.bdxreport.com

Follow your physician's instructions carefully
The patient diary is an important part of this procedure. Use this diary to document any symptoms you experience.
If a high pitched tone continuously repeats, patient should remove the device and notify their physician.
Questions? Contact your Physician

Traveling through airports: Inform screening personnel that you are wearing the Carnation Ambulatory Monitor before going through scanner. Bring this Patient Diary to show security personnel.

Security Screening Statement
This person is wearing a Carnation Ambulatory Monitor (records ECG). It was applied under direction from their physician. The device is currently adhered to the patient's chest and is monitoring their heart.

 Bardy Diagnostics Inc.
Vashon, WA 98070, USA
Call 206.567 .2224

Carnation Ambulatory Monitor
Patient Diary DWG000021 D
10/2014

Applying the Holter Monitors



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- Remove liner from the back of the patch by holding the tab at the top of the device and peel it downwards.
- Hold adhesive patch at the top and bottom to ensure that it does not fold over on itself.
- Make sure chest is clear and free of clothing.
- Place patch on chest to the left of the sternotomy dressing, with bottom of patch at level of the bottom of the ribcage.
- Firmly and carefully rub around edges of the adhesive for 1 minute.



Removing the Holter Monitors



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- Remove the patch from the chest by holding the tab at the top and pulling it downwards.
- Affix the patch onto the outline on the outside of the pouch in which it came.
- Wipe off any excess adhesive from the skin with the adhesive wipe supplied in the box.

Sending to the core lab



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- Complete time/date removed on the diary card.
- Insert the Holter monitor and the completed diary card into the box.
- Print the postage labels supplied and affix to box.

Business Reply
Licence Number
RUCJ-ACKT-GSCK

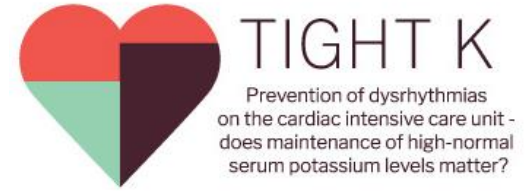
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Tight K Core Lab
Cardiac Diagnostic Unit
Wythenshawe Hospital
Southmoor Road
Manchester
M23 9LT



Requesting resupply



- Further stock to be requested direct from Gary Ham and the Dot Medical team gham@dot-medical.com
- Please copy in tightk@lshtm.ac.uk

Follow up reports from core lab



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- The core lab will analyse the Holters for any arrhythmia.
- Reports of malignant arrhythmias picked up by the core lab will be sent back to the CTU, however this process may take several weeks.
- The CTU will then pass on the information to the research team.
- This should then be fed back to participants primary care team.



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Questions?



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Please contact us with any queries

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