

Can the Werfen GEM Hemochron 100 activated clotting time be used to monitor anticoagulation in prolonged baseline activated partial thromboplastin time?

Submission date 02/09/2026	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 04/09/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 04/09/2026	Condition category Surgery	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

During open heart surgery, patients are given a blood thinner (heparin). Activated partial thromboplastin time (aPTT) is a blood test performed before open heart surgery to see what method should be used to monitor the heparin. The aim of this study is to evaluate the effect a prolonged aPTT has on the different tests available to monitor heparin in patients undergoing open heart surgery who have a prolonged aPTT. Current standard care is to monitor the heparin in these patients using a test carried out in a laboratory in another area of the hospital. This research is to evaluate a test (the GEM Hemochron 100 ACT) that can be used within the operating theatre, removing the need to transport the blood samples to the laboratory, meaning results are available more quickly.

Who can participate?

Patients aged over 18 years with a prolonged baseline clotting time, who are undergoing open heart surgery or attending for a Haematology clinic appointment

What does the study involve?

Participants will have a drop of blood taken from their finger tip to measure their baseline clotting test on the GH100 ACT analyser. Some blood will then be taken from their arm and separated into three tubes, each containing a different amount of anticoagulant. These samples will then have tests performed on them to measure the amount of anticoagulant in them, and they will have clotting times performed on them to measure the affect the anticoagulant has on the clotting tests. Those patients undergoing open heart surgery will have blood samples taken every 30 minutes during surgery and the same tests will be performed on these blood sample. The results from before and during surgery will then be compared to one another, and the amount of anticoagulant given to patients will also be studied.

What are the possible benefits and risks of participating?

By taking part in this study, participants will be contributing to developing a protocol for the

safe management of heparin in patients with prolonged baseline clotting tests undergoing heart surgery.

As we are taking a blood sample from a participants fingertip, it may feel a bit bruised or sore for a day or so after. There may also be a slight bruise from the where the blood was taken from their arm. There are no further risks and participants will always be given standard care as a minimum.

Where is the study run from?

Lancashire Cardiac Centre and Lancashire Haematology Centre, Blackpool Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

September 2026 to September 2027

Who is funding the study?

The National School of Healthcare Science, NHS England (UK) is funding the study and Werfen (Spain) are providing the GH100 analyser

Who is the main contact?

Claire Rowlandson, claire.rowlandson@nhs.net

Contact information

Type(s)

Principal investigator, Scientific, Public

Contact name

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Additional identifiers

Central Portfolio Management System (CPMS)

70061

Study information

Scientific Title

Evaluation of the Werfen GEM Hemochron 100 activated clotting time point of care device in the therapeutic monitoring of unfractionated heparin in patients undergoing cardiopulmonary bypass with a prolonged baseline activated partial thromboplastin time

Study objectives

1. To establish the workflow for spiking whole blood from a non-anticoagulated participant with unfractionated heparin (UFH) ex vivo, to ensure sample integrity is not impacted prior to subsequent testing. The testing will involve performing an ACT, and an extended anti-Xa assay which will inform the workflow for spiking of baseline samples for participants in the main study and control groups.
2. To establish how a prolonged aPTT affects the baseline ACT
3. To establish if there is a significant difference between the concentration of UFH used when measured using GH100 ACT, anti-Xa and HMS+
4. To establish a protocol for monitoring high concentrations of UFH in participants with an abnormal baseline aPTT

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 12/03/2026, East of England – Cambridge Central Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; -; cambridgecentral.rec@hra.nhs.uk), ref: 25/EE/0185

Primary study design

Observational

Study design

Observational case-control study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Patients undergoing cardiopulmonary bypass with a prolonged baseline activated partial thromboplastin time (aPTT)

Interventions

This is a case-control study, utilising and control group of participants and a study group formed from two subgroups, A and B. This methodology has been chosen as the research team are required to be aware of the participant's status with regards to Lupus prior to the study. This is not an interventional study, as all participants will receive standard care regardless of whether they are in the control group or the study group. The control group will be age, sex, weight and ethnicity matched to the study group, aligning the comorbidities as much as possible.

The first step in this project is to test the method for adding the anticoagulant (heparin) to whole blood outside of the body through a small number of participants (pilot study). This will inform the method used for predicting the effect of heparin before a patient has open heart surgery.

Six healthy volunteers will be recruited from NHS staff working within the site where the research project will be carried out. These will be identified via the display of a poster in the Pathology department at the Trust where the study is being undertaken. This poster will contain the contact details of the Chief Investigator in order for interested participants to contact and express their interest. A drop of blood will be collected from their fingertip and tested on the GEM Hemochron 100 (GH100) activated clotted time analyser. 7 ml of blood will be taken from their arm and portions of this blood will be mixed with different amounts of heparin. Once mixed, these portions of blood will be tested using the GH100 analyser and a laboratory test to see if the concentration of heparin can be measured accurately.

A drop of blood will be collected from the fingertip of each participant and tested on the GH100 analyser. This will be before open heart surgery and is standard practice for participants undergoing open heart surgery (subgroup A and control group) but will be an additional sample for participants attending the Haematology diagnostic clinic (subgroup B). These results will be the 'baseline' activated clotting times. The results of the control group and subgroups A plus B will be compared.

Prior to open heart surgery, participants in the control group and subgroup A will have 13 ml of venous blood taken. This blood will be portioned into six aliquots. Each aliquot will have one of three defined concentrations of heparin mixed with the blood, resulting in a pair of aliquots which contain the same concentration of heparin. One of the pair of aliquots will be tested using the GH100 analyser. The remaining aliquot from the pair will be tested using a laboratory test to measure accurately the concentration of heparin in the blood. This will occur for each of the three concentrations of heparin. This process will also be undertaken with the participants attending the Haematology diagnostic clinic (subgroup B). Results of subgroups A and B will be analysed to each other to see if there is any relationship amongst participants with Lupus. These results will also be compared to the results of the control group. Results of the control group and subgroup A will be compared to the results of the control group and subgroup A obtained during the open heart surgery (below) to see if there is any difference, and whether the results can be used to contribute to a standard protocol for the management of patients with Lupus.

During open heart surgery, blood samples will be taken at 20-30 minutes intervals, as per standard care, from participants in the control group and those in subgroup A. These samples will be tested using the GH100 analyser to establish the activated clotting time. Samples will also be sent to the laboratory for testing to establish the amount of heparin in the participant's blood. The care team will also record the weight of the participant, the temperature of the participant, and the details of any heparin the participant receives while undergoing open heart surgery. Results from subgroup A will be compared to the control group to see if there is any difference, and whether the results can be used to contribute to a standard protocol for the management of patients with Lupus.

Intervention Type

Other

Primary outcome(s)

1. Heparin levels in blood measured using an anti-Xa assay on an ACL TOP analyser at baseline and at 30-minute intervals during surgery
2. Activated clotting time measured using the GH100 ACT analyser at baseline and at 30-minute intervals during surgery
3. The level of heparin used or projected to be used, measured using a result proforma at 30-minute intervals during surgery

Key secondary outcome(s)

There are no secondary outcomes

Completion date

30/09/2027

Eligibility**Key inclusion criteria**

1. Aged 18 years or over
2. Capacity to give informed consent
3. Prolonged aPTT (study group only)
4. Not on anticoagulant therapy at the time the baseline activated clotting time (ACT) is taken
5. Undergoing open heart surgery using a heart and lung machine (subgroup A and control group)
6. Attending a Haematology Diagnostic clinic for the investigation of a prolonged aPTT (subgroup B)
7. Normal coagulation screen (control group only)
8. Do not require a translator

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

100 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Under the age of 18 years
2. Does not have capacity to give informed consent
3. Taking anticoagulant therapy at the time of baseline ACT
4. Patients with prolonged aPTT who are not having open heart surgery or attending a Haematology Diagnostic clinic
5. Participants who require a translator

Date of first enrolment

09/09/2026

Date of final enrolment

31/08/2027

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Blackpool Teaching Hospitals NHS Foundation Trust

Victoria Hospital

Whinney Heys Road

Blackpool

England

FY3 8NR

Sponsor information

Organisation

Blackpool Teaching Hospitals NHS Foundation Trust

ROR

<https://ror.org/03444yt49>

Funder(s)

Funder type

Government

Funder Name

National School of Healthcare Science, NHS England

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

