ISRCTN48548060 https://doi.org/10.1186/ISRCTN48548060

Evaluation of the GRI gentleheel® device for adult finger blood sampling

Submission date
02/03/2022

Recruitment status
No longer recruiting

Registration date
03/03/2022

Overall study status
Completed

Last Edited
16/02/2023

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The current 'gold standard' way of obtaining blood from a patient has been through venepuncture, using a needle and syringe to draw blood from the forearm. Venepuncture has several disadvantages. It is resource-intensive, requiring a healthcare professional to carry out the procedure in a hospital or clinic. It has potential complications, including pain, bruising, risk of sharp injury to the healthcare professional, and anaemia related to repeated blood tests. Additionally, some patients have poor circulation, and require multiple attempts in order to obtain blood. This can be especially challenging in those patients with damaged veins (such as burns patients) and those with arms in casts, where venepuncture may then be attempted from the feet, a painful procedure, which can cause further anxiety to the patient.

Capillary blood sampling has been developed as a way of obtaining a smaller blood volume without the need for inserting a needle into a peripheral vein. Labs are now able to process a smaller amount of blood than before. A lancet is used to make a small puncture in the skin of the fingertips, resulting in pinpoint bleeding. This can be ‘squeezed’ into a blood collection tube and sent to the lab to obtain blood results. This technique is not new. In fact, lancets are used regularly by people with diabetes to check their blood sugar levels. Lancet devices are cheaper, less painful, do not require a healthcare professional to obtain blood, are safer and carry fewer risks than traditional venepuncture. However, the volume of blood obtained can be insufficient, and as such patients are often required to prick several fingers to obtain sufficient blood to be sent for analysis.

One of these lancets, called gentleheel® has already been used in hospitals throughout the world for more than a decade to obtain a drop of blood from the heels of newborn children for blood tests. The gentleheel® lancet itself is a plastic box the size of a small matchbox, which comes pre-loaded with a sterile lancet. gentleheel® is simple to use: it is simply held against the side of the fingertip and a button is pressed on the side of the device, deploying the spring-loaded lancet at high speed and piercing the surface of the skin. This results in pinpoint bleeding. The finger is gently squeezed to aid the flow of blood, which is collected in a blood tube. One particular advantage with gentleheel® is its ability to draw more blood from a single prick than other traditional lancet devices. Although gentleheel® has been used in newborns, it has not yet been tested to obtain blood from the fingertips of adults.

Study Aims
The aims of this study therefore are:
1. To assess if gentleheel® can be used by adults to obtain blood from their fingertips for the purpose of blood testing.
2. To assess how painful the procedure is.

Who can participate?
Healthy adult (aged 18 years or older) volunterers.

What does the study involve?
The study involves the use of gentleheel® lancet device to make a finger prick to the middle and ring fingers. This will be carried out in the study centre. At the centre, you will be asked to wash your hands. You'll then cleanse your fingertips with an alcohol wipe. You will use gentleheel® lancet to prick the tip of your finger. You will need to do this on your middle and ring fingers (one at a time). You will then gently squeeze the finger to allow blood to collect in two small blood bottles. The total volume of blood we will collect will be around 1ml (about a fifth of a teaspoon). Once done, you will apply pressure to the tips of your fingers and tell us how much pain you experience when you carried out the procedure, on a scale of 0-10, with 0 meaning no pain and 10 the worse pain possible. Once you are done, you will be free to leave the study centre. Five day later, we will contact you by phone to see how you're getting on, and to check to see if there are any problems with the finger (such as pain). The telephone call marks the end of the study. If however you are experiencing any problems related to the study, you will be able to speak with the study coordinator at any time during the study.

What are the possible benefits and risks of participating?
Benefits:
The future benefits to be gained from this research is the use of the gentleheel® device as a reliable method of obtaining a sufficient volume of blood from a single fingerprick for blood analysis, which can be used as a home-test kit. This would reduce the need for traditional venepuncture for obtaining blood, reduces pain, saves on resources and allows patients to do the procedure by themselves in the comfort of their own homes.
Risks:
1. The risk of pain when using the device. The risk of pain when using a lancet-based device is known to be small. If however, the pain is excessive, then no further finger pricks will take place and you will will not be expected to complete the study.
2. The risk of bleeding from the fingertip taking more than five minutes to stop with gentle pressure and elevation. This risk is very small and in healthy individuals, it is unlikely for this risk to be of concern.
3. The risk of bruising following the procedure. Pressure to the finger and elevating it following the procedure, should minimise this risk.
4. The risk of infection following the procedure. This is a very rare risk in healthy individuals. This risk is minimised by washing the hands and cleaning with alcohol wipes.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
January 2022 to November 2022

Who is funding the study?
Mowgli Innovation (UK)

Who is the main contact?
Dr Yazan Al Ajam, yazan.al-ajam@nhs.net
Georges Haines, georges@drawmore.health

Contact information

Type(s)
Principal investigator

Contact name
Dr Yazan Al Ajam

ORCID ID
https://orcid.org/0000-0002-1153-3238

Contact details
Department of Plastic and Reconstructive Surgery
Royal Free London NHS Foundation Trust
Pond Street
London
United Kingdom
NW3 2QY
+44 20 7794 0500 ext 36988
yazan.al-ajam@nhs.net

Type(s)
Scientific

Contact name
Dr Yazan Al-Ajam

Contact details
Department of Plastic and Reconstructive Surgery
Royal Free London NHS Foundation Trust
Pond Street
London
United Kingdom
NW3 2QY
+44 20 7794 0500 ext 36988
yazan.al-ajam@nhs.net

Type(s)
Public

Contact name
Mr Georges Haines

Contact details
69 Portnall Road
London

United Kingdom
W9 3BB
+44 7806602491
georges@drawmore.health

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
311621

ClinicalTrials.gov (NCT)
Nil Known

Protocol serial number
IRAS 311621

Study information

Scientific Title
Evaluation of the GRI gentleheel® incision device for adult fingertip blood sampling - intended use extension

Study objectives
Gentleheel® can be used as a finger lancet device for capillary blood sampling

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/05/2022, Health & Social Care Research Ethics Committee A (Lissue Industrial Estate West, 5 Rathdown Walk, Moira Road, Lisburn BT28 2RF; +44 (0)28 95361407; RECA@hscni.net), ref: 22/NI/0063

Study design
Prospective interventional non-randomized single-centre study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Capillary blood sampling in adults

Interventions

This is a non-randomised, single-centre study for investigation of gentleheel®, a lancet device that is already CE marked and FDA approved for capillary blood sampling from the heels of neonates.

The purpose of the study is to extend the utility of gentleheel® to see if it can be used as a home kit for obtaining blood from the fingertips in adults.

The aim of our study therefore is to investigate if gentleheel® is able to provide enough blood from a fingertip to fill up to two blood tubes; paediatric haematology (volume 0.5mL) and biochemistry (volume 0.6mL) from a single fingertip puncture, while assessing the user's perception of pain from using the device, and investigate any subsequent adverse events arising from its use.

The design of the study has been chosen after consultation with the product manufacturer, and in line with the current use of existing lancet-based products.

There will be 50 participants in the investigation, with 2 finger incisions per participant, which will result in 100 blood draws.

Eligible participants will be assigned a unique identifier number. Informed consent will be obtained. Any further questions they may have regarding the study will be addressed by the Study Coordinator prior to the start of the study.

Once patients are ready to start the study, they will be taken to their space, which includes a chair where they can sit and a table with all the materials they need to obtain blood. No further help will be given to the participants by the Study Coordinator at this stage to more accurately reflect what would happen when gentleheel® is used as a home test kit. This would also eliminate any possible researcher effects and bias.

The participants will be asked to use the ulnar or radial borders of the middle and ring fingers.

Below is an outline of the steps taken by the the participants to collect blood. The following protocol is based on the recommendations set out by the document "World Health Organisation guidelines on drawing blood: Capillary blood sampling". This step by step guide will also be provided to the participants in the form of a printed sheet on the day of the study.

Material Required:
The following materials will be provided with gentleheel® to each participant on their separate table space:
• Alcohol wipe
• Sterile gauze pads
• Paediatric blood collection tubes x 2, with marker lines to indicate the volume of blood collected.

Preparation:
• Wash your hands under warm water for 2 minutes.
• While standing up swing your arms several times to stimulate the blood flow.
• Use the alcohol wipe to clean the finger you intend to use – we recommend using the middle and ring fingers of your non dominant hand.

Procedure for sample collection:
• Remove gentleheel® from its packaging.

• Remove the trigger lock. Once the trigger is removed, do not depress the trigger or place anything in front of the opening at the base of the device.
• Make the incision: place the opening (at the base of the device) against the cleansed incision site ensuring that the base of the device is flush with the fingertip's skin. After depressing the trigger, immediately remove the device.
• Remove first drop of blood. The first drop of blood should be wiped away from the incision with a dry sterile gauze pad.
• A second drop of blood should form over the incision site. Collect the blood sample and fill it in the collection tube provided. Avoid squeezing the finger too tightly. Fill both blood tubes provided to the fill line.
• When the blood collection procedure is complete, apply firm pressure to the site to stop the bleeding using the dry sterile gauze pad provided.
• Repeat the process on the tip of the other finger.
• Five minutes after you finish the procedure, note down your perception of pain of on a scale of 0-10, with 0 being no pain and 10 the worse possible pain.

Following completion of blood collection and pain scale scoring, the Study Coordinator will collect the blood tubes, and use a calibrated ruler to measure the column of blood in the tube and convert this into microlitres. The site and side of the digit used will be noted.

It is anticipated that the study will take approximately half an hour to complete. Any adverse events which may occur during the study will be documented. These include bruising, bleeding taking more than five minutes to stop and fainting episodes from the lancing procedure. A follow-up telephone call five days after the procedure will be carried out to ascertain any other possible adverse events.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
GRI gentleheel®

Primary outcome(s)
Volume of blood collected (ml) measured after the procedure

Key secondary outcome(s))
Pain measured using the Numerical Pain Rating Scale after the procedure

Completion date
15/11/2022

Eligibility

Key inclusion criteria
1. Subjects older than 18 years (adults).
2. Subjects able to provide informed consent.

Participant type(s)

Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
52

Key exclusion criteria
1. Subjects younger than 18 years.
2. Subjects unable to provide informed consent.
3. Subjects who may be dehydrated.
4. Subjects diagnosed with poor peripheral circulation from other causes.
5. Subjects who present with a callus, skin ulceration, or blister at the intended puncture site.
6. Subjects with thrombocytopenia and/or Platelet abnormalities.
7. Subjects diagnosed with peripheral edema. Pregnancy or breastfeeding (self-reported).
8. Confirmed or suspected malignant cancer.
9. Anxiety with needles or finger pricks.
10. History of blood borne infection (e.g., HIV, hepatitis B or C, syphilis, malaria, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, T lymphotropic virus Type 1, Creutzfeldt-Jakob disease).
11. Currently participating in another study.
12. Donation or loss of 400 mL or more of blood within 4 weeks prior to the start of the study.
13. Any other condition that in the Investigator opinion may negatively influence Subject's participation in the study.
14. Intake of medicines that affect blood coagulability (including anticoagulants such as vitamin K, antivirals and anticoagulants such as heparin, aspirin, thrombin inhibitors, vitamin K antagonists).

Date of first enrolment
14/10/2022

Date of final enrolment
15/11/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King’s College London
Collingwood Street
London
United Kingdom
SE1 1UL

Sponsor information

Organisation
Mowgli Innovation

Funder(s)

Funder type
Industry

Funder Name
Mowgli Innovation

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 1		03/03/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1		03/03/2022	No	No