Participant Information Sheet

The use of gentleheel® lancet to obtain blood from the fingertips of adults

We invite you to take part in our research study

Before you decide whether to take part, it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully. Discuss it with your friends and relatives if you wish. You are free to decide whether or not to take part in this study. One of our team will go through the information sheet with you and answer any questions you have. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

Blood tests are one of the most routinely carried out procedures in the health sector. Until recently, this involved using a needle to puncture a vein, a procedure known as venepuncture. Venepuncture carries potential risks of pain, bruising, sharp injury and anaemia associated with repeat blood tests. An alternative to this is capillary blood testing. This involves the use of a device with a pre-loaded tiny needle that when placed on the finger tip and activated, results in the needle puncturing the skin and causing pin point bleeding. This blood can be collected and used for analysis in the same way as venepuncture-obtained blood. This technique is not new. In fact, people with diabetes routinely use lancet devices to check their blood sugar levels. Capillary blood testing has the advantage of being less painful, requires fewer consumables, and causes less anxiety for the patient.

However one disadvantage of this method is obtaining sufficient blood volume from the fingertip. If too small a sample is used, the labs are unable to process it and another sample needs to be taken. In an attempt to get a sufficient amount of blood from their fingertips, paitents often have to squeeze their fingers quite hard. This excessive squeezing can spoil the blood sample and result in false blood test results. As a result, patients sometimes find themselves having to puncture several fingers to obtain an adequate blood sample.

There is therefore a real need to have a lancet device that is able to provide sufficient blood from the fingertip to allow for reliable blood test processing.

Our solution to the problem is to use a particular lancet device called gentleheel®. This type of lancet has already been on the market for more than ten years, and it is used in obtaining blood from the heels of newborns. This particular type of lancet provides a better blood flow from the finger tip than other lancet-based devices owing to the way the lancet blade is designed. However, gentleheel® has only been used on the heels of newborns by healthcare professionals, and not on the fingertips of adults.

Why have I been invited?

The purpose of this study is to test whether gentleheel® can be used by adult lay members of the public, without the help of a healthcare professional, to obtain blood from their fingertips. We want to find out if we can fill up to two paediatric blood tubes, with a total volume of 1.1mL, less than one fifth of a teaspoon of blood. This volume is adequate to run most of the blood tests that are commonly done. We also want to find out how painful it is to use the device, and what potential side effects might arise from its use (such as bruising). If we find that this device is successful in reliably providing a sufficient blood sample with minimal discomfort to the user, we will have a valid alternative to venipuncture when it comes to blood tests. We are recruiting fifty participants to take part in this study.

Do I have to take part?

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time without giving a reason. This would not affect the standard of care you receive or any future care you may require.

What will happen to me if I take part and what will I have to do?

The study will last for 20-30 minutes at the study centre. Afterward, you are free to leave as the first part of the study will be over. Five days after this we will call you to see how you are doing, and if you are having any problems following the procedure.

We will ask you to come to the study centre on the day you have been allocated. When you arrive, we will go through the procedure with you again and answer any questions you may have. You will be asked to sign a consent form, which is necessary to start the study. Once this is done, you will be taken to your space within the study centre. You will have a chair to sit on, and a table which contains gentleheel®, alcohol wipes, sterile gauze, and two paediatric blood tubes to fill. Each blood tube will have a fill line, which the Study Coordinator will familiarize you with. You need to try to fill each tube to the fill line if you can. We will use the device on the tips of two of your fingers – the middle and the ring fingers. The following is a summary of the procedure you will be performing on each of the middle and ring fingers:

Materials provided with gentleheel®:

- Alcohol wipe
- Sterile gauze pads
- Two blood collection tubes, 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 or ring finger of your non-dominant hand.

Procedure for sample collection

- Either side of the tip of the middle/ring fingers can be used, as indicated in the picture below. The Study Coordinator will make note of which finger and which side you've used. You may use either right or left hand fingers for this, but we suggest using your non-dominant hand (as its easier to use the device with your dominant hand).

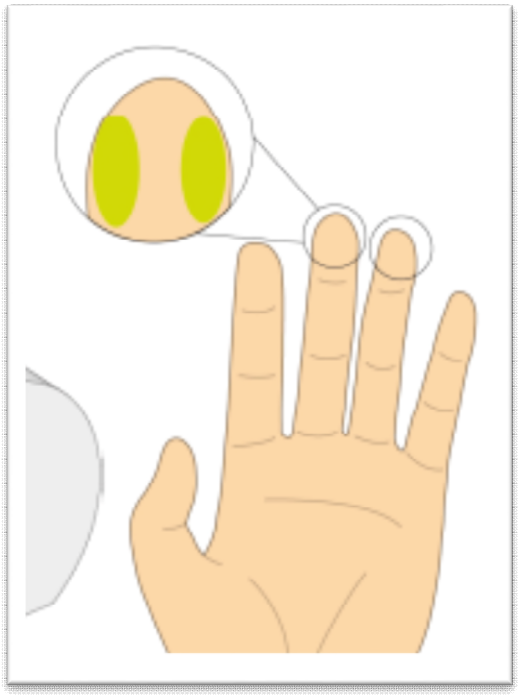

Illustration of fingertip puncture site.

- **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.
- **Puncture.** Place the opening (at the base of the device) against the cleansed puncture 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 puncture site with a dry sterile gauze pad.

- **Collect sample.** A second drop of blood should form over the puncture site. Collect the blood sample and fill it in the collection tubes provided, aiming to go up to the fill line. Avoid squeezing the finger too tightly.
- **Compression.** When the blood collection procedure is complete, apply firm pressure to the site to stop the bleeding using the dry sterile gauze pad provided, and hold it above your heart level.
- Note down your perception of pain (0-10) for each finger.

Expenses and payments

We will reimburse you for your travelling expenses and food. Please keep a receipt of these expenses and forward onto the Study Coordinator.

What are the possible disadvantages and risks of taking part?

The use of gentleheel® is safe, with a proven record in the paediatric medicine for more than a decade. However, there are certain risks associated with the use of gentleheel®, which are the same as for the use of most lancet devices used for capillary blood sampling from the fingertip. These are:

1) The risk of pain when using the device is well documented in lancet-based devices and is known to be small.
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 with no known clotting abnormalities, which is part of the recruitment criteria.
3) The risk of bruising following the procedure. Applying pressure to the finger while raising it above heart-level should minimise this risk.
4) The risk of infection following the procedure. This is a very rare risk and is minimised by cleaning and preparing the skin appropriately prior to the procedure.

What are the possible benefits of taking part?

The future benefits to be gained from this research is the use of the gentleheel® as a 'home-kit' device for capillary blood sampling from the fingertips of adults, addressing the shortcomings of traditional venipuncture.

What will happen when the research study ends?

You will not be expected to have any further appointments with the research team after the study has completed.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. It is possible that we will have to ask you to drop out before you finish the study.

What if there is a problem?

Any complaint about the way you have been dealt with during the clinical trial or any possible harm you might suffer will be addressed. If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this form.

If I have questions or concerns about this study, whom can I speak to?

If you want to speak to someone about the research study, you can contact them using the following details:

Georges Haines
Study Coordinator
georges@drawmore.health
+44 7806602491

Will my data be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The results of this research study may be published in a medical book or journal. However, your name or other identifying information will not be used for these purposes.

Mowgli Innovation is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Mowgli Innovation will keep identifiable information about you for 5 years after the study has finished, in line with established practice. To safeguard your rights, we will use the minimum personally-identifiable information possible.

We will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Mowgli Innovation and regulatory organisations may look at your research records to check the accuracy of the research study. The only ones who will have access to information that identifies you will be people who need to contact you to audit the data collection process. The people who analyse the information will not be able to identify you. We will keep your details encrypted

and will not use them for any purpose other than that related to research and detailed above.

What will happen to the results of the research study?

The results of the study will be available after the study has concluded. We aim for the results to be published in a medical journal or to be presented at a scientific conference. The data will be anonymous and none of the patients involved will be identified in any report or publication. Should you wish to see the results, or the publication, please sign the relevant box of the consent form when agreeing to take part in the study.

Who is funding the research?

Mowgli Innovation partially funds this clinical trial. No doctors will be paid for including you in this study.

Your Privacy Rights

You have the right not to sign the consent form that allows us to use your information for research. You have the right to withdraw your permission for us to use your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study. Once your permission has been withdrawn, you will not be able to continue on the study.

Further information and contact details

You are encouraged to ask any questions you wish, before, during or after your treatment and you can call us with any of your questions or concerns. If you wish to read the research on which this study is based, please ask your Study Coordinator.

Your Study coordinator/manager Email: georges@drawmore.health

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