Depth for Intramuscular Medication injection during Pregnancy to Vastus Lateralis

IRAS reference number: 356744
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We are conducting a study in the maternity unit of Queen Elizabeth Hospital Woolwich and University Hospital Lewisham and would like to invite you to take part. This leaflet provides information about the study, including why it is being performed and what it might involve. Please ask us about anything that is not clear or if you have further questions.
Please be reassured your decision to take part, or not, will not affect the care you or your baby receive. Thank you for taking the time to consider involvement in DIMPL.

What is the purpose of the study?

The purpose of DIMPL is to perform an ultrasound scan of your thigh to measure the distance from the skin to the muscle underneath, called vastus lateralis. We are investigating if this distance is different for patients who are about to or have already given birth, including those living with obesity, compared to the rest of the population.

This is important because during delivery, whether it is vaginal or via caesarean section, healthcare professionals frequently give intra-muscular injections to this muscle, with consent. These medications are usually given to stop bleeding that can otherwise occur. We need to make sure the medication reaches the muscle layer in order for it to work properly. If you agree to take part in the study this does not mean we give you any injections or medications as part of your involvement.

Why have I been asked?

As a patient delivering their baby at Queen Elizabeth Hospital or University Hospital Lewisham you may be eligible to take part in DIMPL. This information can help you decide if you are happy to take part.

Do I have to take part?

Taking part is entirely voluntary. You do NOT need to take part and it is your choice. You may withdraw your consent at any time. If we have already collected the data from your scan before you withdraw your consent then we may keep these details. It is also possible that you have consented to be part of the study but, later on, no longer meet the inclusion criteria, in which case we will not be able to use your information.

What will it involve for me?

1. Whilst you are in hospital for the delivery of your baby, a member of the research team will approach you with information regarding DIMPL. This may be on the labour ward, on the antenatal ward or in the recovery area of theatres, when you feel ready.
2. If you are willing to take part we will ask you to sign a consent form. The research team will be able to give you further information if you need it and answer any questions.
3. A member of the research team will then scan the middle area of your thigh using an ultrasound machine, when you are not in pain and comfortable. They will apply a small amount of jelly to the side of your thigh and put the ultrasound probe on top, to get an image of the muscles in your leg. They will take several minutes to take note of the distance on the ultrasound picture from the skin to the muscle underneath. The scan may take up to 15 minutes to complete.

How will we use information about you?

We will need to use information from you and your medical records for this research project.
This information will include:

- Hospital number
- Date of birth
- Weight
- Body mass index
- Ethnicity
- Gestation or time since delivery
- Results of ultrasound scan of the thigh

People will use this information to do the research or to check the records to make sure the research is being done properly. People who do not need to know who you are will not be able to see your name, hospital number or date of birth. Your data will have a code number instead.
Lewisham and Greenwich Trust Research and Development team is the sponsor of this research. They are responsible for looking after your information.
We will keep all information about you safe and secure by:

- The study information will be collected on paper forms which will be stored in a locked, secure location only accessible by the research team
- Your data will be anonymised using a code number
- Anonymised data will be uploaded to a locked, secure NHS computer only accessible by the research team
- Your data will not be shared outside the UK.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will keep your study data for 5 years as per the Lewisham and Greenwich Trust policy. During this time it will be archived in the trust's secure facility. The study data will then be destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can you find out more about how your information is used?

You can find out more about how we use your information through the following routes:

- The NHS GDPR leaflet at www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team
- By sending an email to dimple study.lgt@gmail.com
- By ringing us on 07443516699 or 07812988613

What are the possible benefits to me of taking part?

This study will not change your care, and therefore will not benefit you directly. We hope the study will provide benefit for future patients and could therefore benefit you if returning for future pregnancies.

What are the possible disadvantages or risks of taking part?

We do not think there are any risks to taking part. There is a small chance if you have a bruise on your thigh that it may feel sensitive to have pressure applied with the probe. However, we can use either leg to avoid this. Ultrasound imaging is safe and does not have any side effects. The main disadvantage to you is the time it requires to be involved. We anticipate the scan will take up to 15 minutes. You may be undergoing the scanning process once you have already given birth. If this is the case then the scan will not interfere with you holding, feeding or bonding with your baby. You will be able to do all of these throughout the short scanning process. There are no risks at all to your baby for taking part either before or after delivery.

What will happen to the results of the study?

We hope this study will result in written and oral publications. If you wish to receive copies of these then you can provide your email address below. At no point will these publications be able to identify you as a participant.

Who is funding and organising the study?

This study has been set up by two NHS staff members who are not affiliated with other organisations. Their details are at the top of this sheet. A small amount of funding has been provided by the Lewisham and Greenwich Research and Development Department.

What do I do if I wish to make a complaint?

You can raise concerns and complaints via the usual hospital complaints system. This is called the Patient Advice and Liaison Service (PALS). You can also raise any issues with the local research team or the Chief Investigator whose details:

Dr Richard Crowson - Chief Investigator at dimple study.lgt@gmail.com