

DIMPL

Depth for Intramuscular Medication injection during Pregnancy to Vastus Lateralis DIMPL

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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 for you. Please ask us about anything that is not clear or if you have further questions. Hopefully this leaflet may help you decide if you are willing to participate in this study.

Please be reassured your decision 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 measure the distance from the skin of your mid thigh to the muscle underneath, called vastus lateralis. During delivery, whether it is vaginal or via caesarean section, healthcare professionals frequently administer intra-muscular injections to this muscle, with your consent. In order to make sure the injection is administered to the right place we need to know how deep the muscle is. This will help us ensure the medication is delivered to our patients effectively.

Why have I been asked?

As a patient delivering their baby, via either vaginal or caesarean section, at Queen Elizabeth Hospital Woolwich or University Hospital Lewisham you may be eligible to participate in DIMPL. This information sheet is designed to 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 if you wish to participate or not. You may withdraw your consent to participate at any time. If we have already collected the data from your scan before you withdraw your consent then we may keep these details.

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 participate 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 study team will then scan the middle area of your thigh using an ultrasound machine. They will apply a small amount of jelly to the side of your thigh and put a 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.

What will happen to my information?

The study team will collect some information about you including demographics such as ethnicity, weight and how many weeks pregnant you are/were. This information, including your scan results will initially be collected on paper forms. These forms will be stored in a locked, secure location only accessible by the study team. We will anonymise your data using a code number. It will be uploaded to a locked and secure NHS computer, again only accessible by the study team. The paper forms will be destroyed in confidential waste. The computerised data will be kept for 5 years as per the Lewisham and Greenwich Trust policy.

How will we use your information?

We will use your data to investigate the depth from the skin of your outer thigh to the muscle below it. The study team will analyse your data once it is anonymised. Your anonymised data will, at some point, be used to publish research on this topic. Other researchers may review the anonymised data to ensure the research has been carried out to a high standard. No one will be able to access information which identifies you.

What are the possible benefits to me of taking part?

This study may not benefit you directly during this pregnancy however our aim is to improve our delivery of intra-muscular injections for all pregnant patients giving birth to ensure they will be maximally effective. This could have a positive benefit for you for future pregnancies. We hope it will provide benefit for other future pregnant patients giving birth

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 ultrasound. However, we can use either leg to try and 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 in the study. We anticipate for the consent process and the scanning process this will be no more than 15 minutes.

What will happen to the results of the study?

We hope this study will culminate in written and oral publications. If you wish to receive copies of these then you can provide your email address below or please indicate if you would like to receive these by post. 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 Queen Elizabeth Hospital 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 study team or the Chief Investigator whose details are at the top of this sheet.