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Investigating skin-to-thigh muscle depth in pregnant patients for medication injections

Submission date
27/06/2025

Recruitment status
Recruiting

Registration date
24/07/2025

Overall study status
Ongoing

Last Edited
04/02/2026

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
During caesarian section or vaginal birth medications are occasionally required to be given to the patient. Some of these medications are required to be given via a small needle into the side of the leg. The muscle that the medication is aiming to reach is called the 'vastus lateralis' muscle. This study aims to measure the distance between the skin and this muscle using a simple ultrasound scan. By knowing this measurement, it will help to ensure that these medications are reaching the muscle appropriately for our patients. This is a non-invasive scan and will not impact individual patient care.

Who can participate?
Participants can be any patient aged between 18 and 55 years of age who are attending either Queen Elizabeth Hospital or University Hospital Lewisham, which are both hospitals that are part of Lewisham and Greenwich NHS Trust, for a caesarian section or who are in labour.

What does the study involve?
The study involves a simple ultrasound scan of the side of the leg. This will take approximately up to 15 minutes to perform by one of the research team members who is trained to perform the scan. The scans will be performed for women who would like to be involved in the study who are either in the labour process, any pregnant patient on the day of their c-section, before the procedure or within 2 hours after the baby has been delivered. The study team will also collect some information about the patient, including demographics such as ethnicity, weight and how many weeks pregnant the patient is.

What are the possible benefits and risks of participating?
This study may not benefit the patient directly during their current pregnancy; however, the aim is to improve the delivery of intramuscular injections for all patients giving birth to ensure they will be most effective. This could have a positive benefit for the individual patient in future pregnancies.

The study team do not think that there are any risks in taking part in this study. There is a small chance that if the patient has a bruise on the 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 the patient is the time it requires to be involved in the study. The scanning process is anticipated to take up to 15 minutes to perform and will not impact patient care on the day.

Where is the study run from?
The study will run at both Queen Elizabeth Hospital and University Hospital Lewisham, which are both part of Lewisham and Greenwich NHS Trust.

When is the study starting and how long is it expected to run for?
January 2026 to May 2026

Who is funding the study?
The Lewisham and Greenwich NHS Trust, UK

Who is the main contact?
Dr Richard Crowson (MBChB FRCA BSc), richard.crowson2@nhs.net

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil Known

Integrated Research Application System (IRAS)
356744

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Depth for intramuscular medication injection in pregnancy to the vastus lateralis

Acronym
DIMPLE

Study objectives
With an increasing number of patients living with obesity in our population, at a certain body mass index (BMI), the distance between the skin and the vastus lateralis muscle (the muscle within the lateral thigh most commonly used to deliver intramuscular medication in pregnancy) might increase. This might impact the delivery of medication intended to reach this muscle. Thus, using standard needle lengths commonly used in clinical practice at a certain BMI, the medication might be injected into the adipose tissue as opposed to the intended muscle layer.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/12/2025, West Midlands-Black country research and ethics committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071049178; blackcountry.rec@hra.nhs.uk), ref: 5/WM/0200

Study design
Observational basic science measurement study

Primary study design
Observational

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Distance between skin and vastus lateralis muscle in pregnant patients

Interventions
Current interventions as of 14/11/2025:

Basic bedside ultrasound scans will be performed to obtain measurements of the lateral thigh of patients attending for elective caesarean section and patients in labour on the maternity ward at both sites of Lewisham and Greenwich NHS Trust (Queen Elizabeth Hospital and Lewisham Hospital).

Anaesthetists at both sites who have volunteered to assist with data collection will be trained to perform the non-invasive bedside scan with the same standardised technique. This will be performed at the middle third of the lateral leg at a 45 degree angle with a 'reasonable application of pressure.' Once trained, this scan will take up to 15 minutes to perform. The scans will be performed on consented patients on the day of their elective caesarean section prior to surgery or within 2 hours of delivery and on any patient undergoing the labour process on the maternity wards.

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Previous interventions:

Basic bedside ultrasound scans will be performed to obtain measurements of the lateral thigh of patients attending for elective caesarean section and patients in labour on the maternity ward at both sites of Lewisham and Greenwich NHS Trust (Queen Elizabeth Hospital and Lewisham Hospital).

Anaesthetists at both sites who have volunteered to assist with data collection will be trained to perform the non-invasive bedside scan with the same standardised technique. This will be performed at the middle third of the lateral leg at a 45 degree angle with a 'reasonable application of pressure.' Once trained, this scan will take less than 5 minutes to perform. The scans will be performed on consented patients on the day of their elective caesarean section prior to surgery or within 2 hours of delivery and on any patient undergoing the labour process on the maternity wards.

Intervention Type
Other

Primary outcome(s)
The distance measured in millimeters (mm) between the skin and vastus lateralis muscle measured using bedside ultrasound scanning at one time point

Key secondary outcome(s))
Body mass index (BMI) calculated using the weight in kgs divided by the height in metres squared, measured using data recorded in the clinical notes system (iCare) during the initial booking appointment (usually within 10 weeks of being pregnant)

Completion date
05/05/2026

Eligibility

Key inclusion criteria

Patients included will be patients presenting for elective caesarian section (c-section) or who are in the labour process

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 13/11/2025:

1. Any patient who does not consent to be part of the study
2. Any patient who is over 2 hours post-delivery from a caesarian section (c-section)
3. Confirmed pre-eclampsia
4. Cardiac disorder
5. Kidney disease
6. Patients taking diuretic medication
7. Any patient with multiple gestation (carrying 2 or more babies)

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3. Confirmed pre-eclampsia
4. Cardiac disorder
5. Kidney disease
6. Patients taking diuretic medication

Date of first enrolment
15/12/2025

Date of final enrolment
05/05/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Elizabeth Hospital
Woolwich Stadium Road
Woolwich
London
England
SE18 4QH

Study participating centre
Lewisham and Greenwich NHS Trust
University Hospital Lewisham
Lewisham High Street
London
England
SE13 6LH

Sponsor information

Organisation
Lewisham and Greenwich NHS Trust

ROR
https://ror.org/05tn2bq24

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Lewisham and Greenwich NHS Trust

Results and Publications

Individual participant data (IPD) sharing plan

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?
Participant information sheet	version 1.2	06/11/2025	13/11/2025	No	Yes
Participant information sheet	version 2.2	08/12/2025	18/12/2025	No	Yes