ISRCTN56917791 https://doi.org/10.1186/ISRCTN56917791

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
24/07/2025

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 5 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 pregnant 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. Both the consent and scanning process are anticipated to take no more than 15 minutes 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?
June 2025 to October 2025

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

Contact name
Dr Richard Crowson

Contact details
Queen Elizabeth Hospital
Stadium Road
Woolwich
London
United Kingdom
SE18 4QH
+44 (0)7812988613
richard.crowson2@nhs.net

Type(s)
Public, Scientific

Contact name
Dr Imogen Glover

Contact details
Queen Elizabeth Hospital
Stadium Road
Woolwich
London
United Kingdom
SE18 4QH
+44 (0)2088366000
imogen.glover@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil Known

IRAS number
356744

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

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

Acronym
DIMPL

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)
Not yet submitted, Ethics committee name not provided (Address not provided, City not provided, Zip/postal code not provided; Telephone number not provided; Email@notprovided.com), ref: Reference number not provided

Study design
Observational basic science measurement study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Efficacy

Participant information sheet
See study outputs table

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

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

Secondary outcome measures
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)

Overall study start date
27/06/2025

Completion date
13/10/2025

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Female

Target number of participants
100

Key exclusion criteria
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

Date of first enrolment
04/08/2025

Date of final enrolment
13/10/2025

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
Lewisham and Greenwich NHS Trust
University Hospital Lewisham

Lewisham High Street
London
United Kingdom
SE13 6LH

Sponsor information

Organisation
Lewisham and Greenwich NHS Trust

Sponsor details
Queen Elizabeth Hospital
Stadium Road
Woolwich
London
England
United Kingdom
SE18 4QH
+44 (0)2088365972
karen.corbett-smith@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.lewishamandgreenwich.nhs.uk/

ROR
https://ror.org/05tn2bq24

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Lewisham and Greenwich NHS Trust

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal and presentation at a national anaesthetic conference

Intention to publish date
29/09/2026

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?
Participant information sheet			30/06/2025	No	Yes