

Appendix 13.1 Standard Operator Procedures (SOP) 1- Physical examination and ultrasound scan technique

This SOP describes the procedure of the physical examination and ultrasound scan technique, and the steps that will be followed by the clinicians/researchers, to inform and prepare the participant for the data collection.

A) Physical examination using inspection & digital palpation

The visual inspection and digital palpation will be carried out by one of the two study research nurses.

Equipment (for examination):

- Marker pen
- Gel
- Examination lamp with an adjustable neck

Prior to the examination

- Ensure the room is warm to prevent participant chilling (this ensures participant comfort and also prevents shivering and muscle tension, which can interfere with the examinations).
- Explain the procedure to the participant and check informed consent has been provided
- Reminded the participant they are welcome to ask any questions – before, during or after the procedure – whether they relate to the science or the procedure
- Participants will be made aware that the researchers will adhere to universal precautions to ensure safety during this data collection
- Wash hands thoroughly

Positioning:

- Supine position (lying down):

The participant should initially be lying down on their back (to relax abdominal muscles) with knees bent (to relax thigh {quadriceps} muscles), and arms folded over chest (to relax arm muscles).

- Standing position: ask the participant to stand and arms folded over chest, to ensure that further LH is not identified.

Method:

- Inspect the site with the lamp first. The light should be shined onto the skin surface at an angle of 30-45 degrees (obliquely – not overhead) adjusting its angle to be able to detect any subtle risings or depressions across the surface of the skin.
- Ensure hands are washed and warm, apply a water based gel to the site to facilitate palpation of the area especially if there are no visible changes or lumps in the site.
- Palpate the area using slow circular and vertical fingertip movements followed by repeated horizontal attempts on the same spot (see figure x).
- Start with light pressure and increase thereafter to ensure that deeper tissue changes are felt.
- Perform the 'pinch' maneuver shown in Figure A to further identify LH changes. Comparing the thickness of the suspected spot to that of surrounding areas
- Record the position of any tissue changes carefully on the case report form.

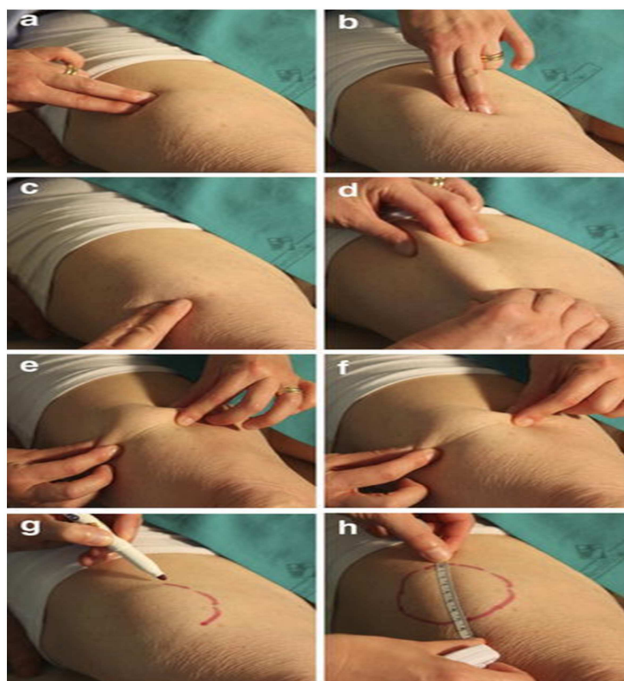


Figure A. Digital palpation of injection sites. Perform repeated vertical and horizontal fingertip movements over and around the area (a–c), ‘pinch’ gently vertically and horizontally across the area to further facilitate identification of LH (d–f). Marking (g) and measure it if not continuing to ultrasound (h) Gentile et al. (2016).

Ultrasound Scan

This SOP is to be used only after the researcher/clinician has completed basic training in the use of ultrasound

The ultrasound scans will be performed by a trained and experienced ultrasonographer.

Equipment

- SonoSite X-Porte with high-frequency linear probe (6–13 MHz)
- Ultrasound gel

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Scanning technique

1) Triceps scan

Patient sits resting both arms across the chest or, alternatively, with both arms resting on the abdomen. Place the transducer in a transverse plane on the posterior and lateral aspect of the upper arm (right and left), two finger-widths below the acromion and sweep up and down to two to four finger-widths (depending on patient limb length and extent of soft tissue in the area) above the elbow (Images A and B).

Image A: Arrows: lateral side of the triceps; lines: two fingers below acromion and two or four fingers above elbow



Image B: Arrows: posterior side of the triceps; lines: two fingers below acromion and two or four fingers above elbow

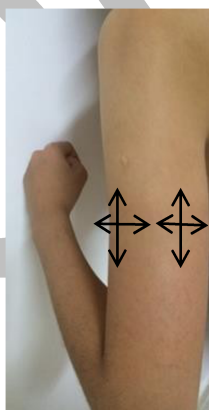


Image C: Arrows: midline of the posterior and lateral aspect of the triceps

Images will be recorded of any tissue changes thought to be LH. Nodules or diffuse areas will be measured and recorded. An image will also be recorded for the posterior and lateral side of both arms, on the midline of the triceps (Image C). If the triceps is being used as an injection site and tissue changes are measured, then an area showing normal skin and tissue depth and type will also be recorded either above or below the injection site in the midline to collect data on epidermal, dermal and subcutaneous tissue.

2) Abdominal scan

With the patient supine, place the transducer in a longitudinal plane over the outer margin of the right hypochondriac region to examine the upper abdominal area, and then sweep side-to-side to the outer margin of the left hypochondriac region. When the transducer is moved by sliding, the angle of entry should remain fixed so that a series of parallel planes can be scanned.

The transducer should continue to the lower abdominal area and begin scanning from the outer margin of the right lumbar region to the outer margin of the left lumbar region (Image D).

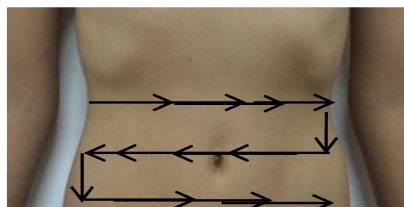


Image D: Arrows: RT and LT hypochondriac region and RT and LT lumbar region

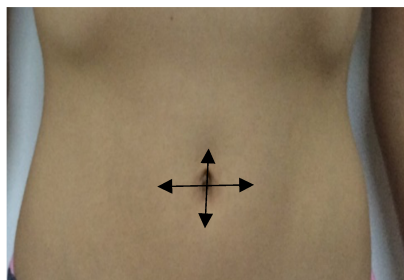


Image E: Arrows: at the midsternal line and the height of the iliac crest avoiding the umbilicus

Images will be recorded of any tissue changes thought to be LH. Nodules or diffuse areas will be measured and recorded. An image will also be recorded and saved of the tissue in the midline at the height of the iliac crest (image E). If this is being used as an injection site – an area of none injected tissue as close as possible to this will be recorded to collect data on normal tissue depth and type in the abdomen.

3) Thigh scan

With the patient supine, place the transducer in a transverse plane, two to four finger-widths above the knee (depending on limb length and soft tissue area), and sweep up and down to the base of the iliac region to scan the anterior side of the thigh (right and left) (Image F).

To scan the lateral side of the thigh (right and left), the patient should be in a lateral recumbent position.



Image F: Arrows: two to four finger-widths above the knee and the base of iliac region

Images will be recorded of any tissue changes thought to be LH. Nodules or diffuse areas will be measured and recorded. An image will also be recorded for the anterior and lateral side of both thighs, on the midline of the midline of the thigh (Image F). If the thigh is being used as an injection site and tissue changes are measured, then an area showing normal skin and tissue depth and type will also be recorded either above or below the injection site in the midline to collect data on epidermal, dermal and subcutaneous tissue.

4) Gluteal region scans:

With the patient on lateral (Right or Left) decubitus position, place the transducer in a longitudinal plane, over the outer side of the right gluteal area and sweep it side to side to the midline. Follow the same technique to scan the left gluteal area (As shown in image G below).

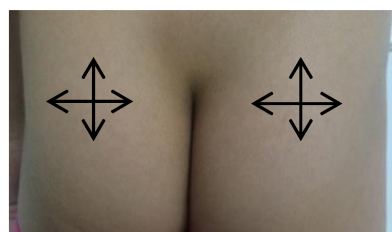
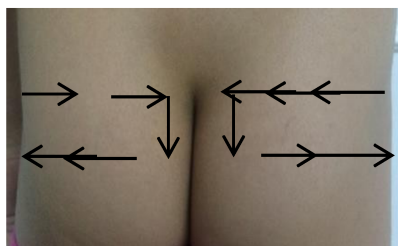


Image H: The midline at the right and left of the posterior inferior iliac spine

Images will be recorded of any tissue changes thought to be LH. Nodules or diffuse areas will be measured and recorded. An image will also be recorded and saved of the tissue in the midline at the right and left of the gluteal area (image H). If this is being used as an injection site – an area of none injected tissue as close as possible to this will be recorded to collect data on normal tissue depth and type in the Gluteal area.

Measurement procedure

The normal subcutaneous tissue and skin thickness will be measured for all identified injection site.

Dermis layer: measured from the lower border of the epidermis and to the upper border of the subcutaneous tissue.

Subcutaneous tissue (SC): The layer between the dermis and the muscle fascia. The SC layer will be measured from the lower border of the dermis layer to the upper border of the muscle.

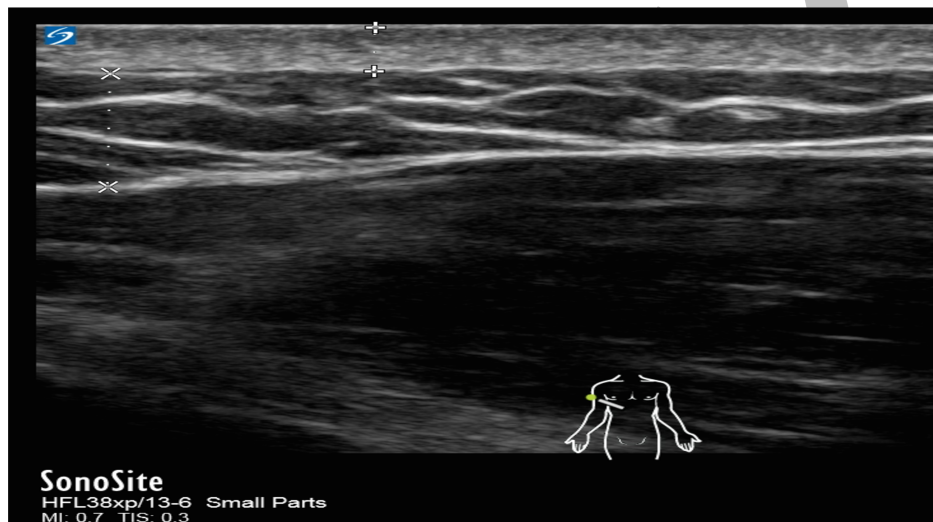


Image 1. (+) the distance from the lower border of the epidermis and to the upper border of the SC. (x) the distance from the lower border of the dermis layer to the upper border of the muscle.

Lipohypertrophy (LH): When the site of LH is identified, the nodule may not have clear edges. For that reason, images should be obtained in both longitudinal and transverse planes to maximise information and accuracy of localisation (Kaplan *et al.* 1990).



Image J. LH measure

Risks

Participants-There is a risk of discomfort during the physical examination and ultrasound scan. This discomfort will be related to examination.

Researchers-There are no known risks to the researchers implementing the SOP as a result of the protocol itself, or the equipment.

Ultrasound scan- There are no known risks from the sound waves used in an ultrasound scan. It does not involve exposure to radiation. External ultrasound scans are generally painless

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[*] I acknowledge that as the chief investigator/faculty supervisor I am responsible for updating this SOP and notifying the Ethic committees if any of the procedures as outlined above change or require revision.

References:

Gentile S., Guarino G., Giancaterini A., Guida P. & Stollo F. (2016) A suitable palpation technique allows to identify skin lipohypertrophic lesions in insulin-treated people with diabetes. *Springerplus*, 5(1), 1-7.

Kaplan P.A., Matamoros A. Jr. & Anderson J.C. (1990) Sonography of Musculoskeletal System. *AJR AMJ Roentgeno*, 155(2), 237-245.