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MUSCLE TISSUE BIOPSY NUTRITION CENTRES

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1. Scope

This procedure is to be followed by the ECRIN Nutrition Centres when performing muscle tissue biopsy.

This procedure is used to describe the technique of the muscle tissue biopsy with needle or tweezers, taking a minimum of 50 mg of muscle tissue in the external vastus lateralis muscle of the thigh for the study of oxidative stress and gene expression analysis.

2. Responsibilities

It is the responsibility of the Management team in the Nutrition Centres to ensure that this procedure is adapted and followed.

3. References

- SOP Skeletal Muscle Biopsy University of Las Palmas de Gran Canaria, Institute of Biomedical Research. Luis Serra
- SOP Skeletal Muscle Biopsy A.Rivelles
- SOP Muscle Biopsy Technique for vastus lateralis
- Mode opératoire : Biopsie de tissu musculaire à l'aiguille CRNH-RA-Version 001, CHLS Pierre Bénite- France
- Mode opératoire : Biopsie de tissu musculaire à la pince CRNH-RA-Version 001, CHLS Pierre Bénite- France

4. Terms, definitions, abbreviations

ECRIN: European Clinical Research Infrastructures Network

SOP: Standard Operation Procedure

5. Documentation

6. General

The purpose of this Standard Operation Procedure is to ensure that the process of muscle tissue biopsy with needle or tweezers for Nutrition Centres is performed under standardised conditions.

7. Safety Considerations

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• <u>Please remember that all procedures that involve contact with a biopsy area must</u> be done under sterile conditions.

a) For Staff handling biopsy

- Gloves must be worn when handling a biopsy.
- It is recommended that any member of staff handling a biopsy are vaccinated against Hepatitis B.
- A laboratory coat is worn and safety glasses and a mask should be available for staff if required.
- Used needles and syringes must be discarded into a puncture-resistant sharps container.
- Cover all non-intact skin exposed to patient blood or body fluid with a waterimpermeable occlusive bandage.
- Remove all personal protective equipment before leaving the laboratory or work area.

b) For Patient

- Check for the absence of abnormal coagulation and allergies to local anaesthetics.
- Check for the absence of contraindicated treatments.

8. Sample Requirements

Biopsies must be clearly and permanently identified (with labels or permanent marker) with the information required by the local laboratory: subject's first and last names, hospital number, date of birth and date and time when the sample was collected.

9. Materials

a) For Asepsis

Standard cleaning equipment for trans epidermal biopsies:

Sterile water

Disinfectant solution,

Single use gloves,

Compress & cleaning swabs,

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A single use shaver if required

b) For anesthesia

Sterile gloves

20 ml anaesthetic agent without adrenergic addition (Lidocaïne - Lignocaine)

10ml syringe

Subcutaneous needle

Intramuscular needle

c) For Biopsy

A fenestrated sterile field

A scalpel

Sterile wound dressing including steristrips and a compression bandage.

For needle biopsy

A sterile biopsy needle kit.

For Clamp Biopsy

A sterile muscle biopsy kit including the Weil Blakesley tweezer's

d) For storage of tissue sample

Kidney bowl and tweezers (for the removal of muscle tissue from the needle)

Sterile labelled cryovial,

A liquid nitrogen tank depending on storage post biopsy

Dispatch note

Laboratory forms

10. Patient preparation

- The patient is lying in a bed in underwear and/or hospital gown.
- Explain the procedure with the subject.
- Make the subject comfortable in a semi-recumbent / supine position on the bed.

Location of the biopsy:

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• Decide on the chosen leg and biopsy site. Asking the subject to tense their thigh to identify the area of the vastus lateralis (1/3 from the knee of the distance hip to the knee).

Asepsis of the selected area

- Wash hands.
- Clean with disinfectant solution.
- Shave if required.
- Rinse with Sterile water.
- Clean with disinfectant solution again.

11. Anesthesia

- Wash hands.
- Wear single use gloves.
- Draw up 10ml of anaesthetic agent into 10ml syringe.
- !!! DO NOT DRAW UP AND GIVE WITH THE SAME NEEDLE !!!
- !!! MAXIMAL DOSAGE OF LIGNOCAINE FOR LOCAL ANESTHESIA IS 3mg/kg, BUT NOT TO EXCEED 200mg !!! 200mg IS EQUIVLENT TO 4X5ml VIALS of 1% LIGNOCAINE !!!
- Inject subcutaneously lidocaine just under the the skin around the proposed incision site using intramuscular needle (to numb the skin surface) and by step inject anesthesia vertically into the deeper subcutaneous layers, following the proposed path of biopsy needle insertion, starting at the level of the fascia (but great care not to infiltrate the muscle) and gradually withdrawing the needle upwards.
- Anaesthetic will be deposited on the fascia at the puncture area on a length of less than 1 cm.
- If anaesthetic is required more laterally or medially, bring needle to the subcutaneous level before altering the angle of insertion. Infiltrate tissue as before.

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• Wait about 5 to 10 mins

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- Care taken with placing the anaesthetic can reduce lignocaine dosage to the volunteer whilst not compromising the effectiveness of the anaesthesia.
- Avoiding excess lignocaine dosage is important as lignocaine causes vasodilation and as such will increase post biopsy bleeding, and in muscle will alter metabolic processes, which may affect data obtained from the muscle biopsies.

12. Sampling

- Wash hands with iodine solution
- Wear sterile gloves and cloth
- Open sterile field and place under chosen leg and open consumables onto field.
- Clean with iodine solution the selected area again.
- Make an incision in the skin using the scalpel blade, cutting vertically down to the muscle fascia along the proposed path of the biopsy needle. Keep incision as small as possible to keep trauma / bleeding to a minimum.
- For Needle biopsy, ask a colleague to open suction equipment and to hold suction syringe and place its end into the top of the biopsy needle.
- For tweezer biopsy, ask a colleague to open the Weil Blakesley tweezer's
- Ensure subject is relaxed and knows to expect the sensation of pressure whilst the sample is being taken.
- Explain the importance of keeping their leg as relaxed as possible during the procedure
- The duration of sampling should not take more than 2 minutes.

The taking of the muscle tissue:

a) For Needle biopsy

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- The biopsy needle is inserted through the incision and down into the muscle, through the fascia.
- Once in the muscle, it is important to minimise the movement of the needle within the leg.
- Pull the centre of the needle up by an inch. This allows the window in the needle to open the centre of the needle is depressed and the cut piece of muscle will remain in the barrel of the needle.
- A small turn of the needle can be made and another snip taken.
- Two snips should be taken, and ensuring that the two pieces of the needle are held closed, the whole needle is withdrawn and either frozen immediately in the liquid nitrogen, or dissected and then frozen (according to protocol / analysis requirements).
- The time between entering the leg and removing the needle usually takes between 5 and 7 seconds.

b) For Weil Blakesley tweezer's biopsy

• The Weil Blakesley tweezer's is then introduced in the closed position to the muscle. The tweezer is then opened and removed quickly. The doctor checks that the biopsied tissue is muscle and not fat. Otherwise a new sample is taken.

If the tissue is muscle, a colleague retrieves it immediately and collects it with a sterile needle and places into the labelled cryotube then it is immersed in the liquid nitrogen as quickly as possible.

The time between sampling and immersion in the liquid nitrogen should be less than 2 minutes.

13. Dressing the wound

- A swab is placed over the incision site and firm pressure applied with the palm of hand for at least 5 minutes to reduce bleeding within the tissues.
- After 5 minutes and if no further bleeding is seen, the incision is closed with a sterile steristrip.

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- Place the first steristrip perpendicular to the incision site and the following ones in a star formation. Ensure skin edges are brought fully together to reduce scarring. Use a sterile swab to press down over the incision to ensure adequate adhesion of the steristrip to the skin.
- Use a compression bandage to cover the steristrips.

14. Advice to patient

- The dressing should be kept for 5 days
- Do not wet the dressing (showers allowed, bath prohibited)
- No aspirin allowed for at least four days after the biopsy. For pain, take paracetamol
- Do not practice any sport for 4 days after the biopsies
- Tell the subject to expect some bruising, which should disappear within a week.
- Provide a wound dressing replacement kit to the patient including disinfectant solution, sterile strip and a compression bandage.

15. Disinfection of equipment

As soon as the biopsy is performed, the instruments are rinsed with water and then disinfected with a disinfectant.

The instruments are then brushed, rinsed thoroughly with water, dried with paper towels and placed in a sterilization bag to be sent for sterilization.

16. Transfer of biopsy

Biopsies are stored at -80°C or in liquid nitrogen or transported to the corresponding laboratory for analyses. Transport documents including the dispatch note are attached to all the samples and archived in the laboratory.

17. Limitations & Pitfalls of the Examination

N/A

18. Method Validation

Local methods

19. Procedure Notes & Other Pertinent Information

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N/A

20. Appendices

N/A