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FACET INJECTION STUDY

Injection Manual

Recruiting Site:

Name of PI :

Version 1.0 Date 19 Dec 2014

Authors, on behalf of the Facet Injection Study team:

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Contact details and further information

Following completion of the Facet Injection Study Consensus Conference, this manual has been developed by the FIS team including co-applicants who have responsibility for performing facet joint injections on a regular basis.

If you require further information or support during the trial please contact:

Facet Injection Study team via email : FIS@warwick.ac.uk

Introduction

The use of a corticosteroid/local anaesthetic combination is commonly used as a treatment of facet joint pain. There is, however, little agreement on which drugs should be included in facet joint injections or indeed the overall procedure of injection.

Many techniques are not specific and choices may well be grounded in no more than custom and practice. To address this issue for the purpose of this study the FIS project team systematically identified the available literature on the injection of facet joints to establish the agreed technique for injection. While the data suggests many reports of individual techniques for the therapeutic injection of lumbar facet joints, there is little consensus and no guidelines or recommendations for current best practice. The purpose of our systematic review was to report on the evidence of techniques, practices and processes recommended and used in current clinical practice to administer fluoroscopically guided therapeutic facet joint injections to patients with facetogenic low back pain.

It can be seen from these data that whilst the combination of corticosteroid and local anaesthetic is commonly advised, there is no consistency in relation to injection technique, the choice of drug or doses used. As part of the systematic review, data was extracted from articles or texts and summarised within the Consensus Conference package (Ref - copy available within the Trial Master File and Investigator Site Files).

In June 2014, the Facet Injection Study project team held a Consensus Conference to inform several aspects of the trial design. One aspect addressed was injection technique. Based on our review of the literature and the deliberations of our independent experts within the consensus conference and discussion with the experts performing injection at the participating hospitals, the injection technique has been developed.

For this study we need to achieve a single, detailed process for therapeutic injection of lumbar facet joints that is acceptable to the professional community, and can be applied consistently across all participating study centres. Therefore the facet joint injection manual used in this trial has been drawn from the available evidence base and following consensus gained from a range of experts and clinicians.

Investigational Medicinal Product

For this clinical trial, 1ml of Levobupivacaine 5mg/ml and 1ml of Triamcinolone 10mg/ml administered for the facet joint injection procedure are being used as the Investigational Medicinal Products (IMP).

The pharmaceutical form of Levobupivacaine 5mg/ml and Triamcinolone 10mg/ml is solution for injection.

Dispensing of IMPs will not involve pharmacy as the IMP is routine commercially available stock held within each of the participating hospital's theatres, x-ray department or an equivalent location where the injection is performed. No additional controls are needed above those that are already in place for the IMP is in everyday use.

All IMP will be taken from commercially available stock and each investigator administering the IMP is responsible for ensuring the IMP and other materials required for the injection are correctly received, recorded, handled and stored safely in accordance with local clinical and pharmacy practice and applicable regulatory guidelines.

The FIS study team will support with provision of associated documentation to record the IMP management process accordingly, and where available, will include the local hospital site or Trust clinical trials pharmacy/pharmacist as part of the investigator site team to ensure oversight of the local IMP management procedures.

Facilities

The location for the injection procedure will be as per standard clinical routine. Within participating Trusts, the injection procedure is performed either within a dedicated theatre space, X-ray department or cardiac catheter suite depending on the individual Trust's site practice. Resuscitation equipment must be available at all times within the facilities where the trial facet joint injection procedure is undertaken.

Pre-injection procedures

Prior to or at the latest on the day of the injection procedure, the investigator responsible for the injection must ensure the participant's trial case report form (CRF) is completed with confirmation of the diagnostic assessment outcome and eligibility to join the study. The participant's written informed consent form should be available for the investigator to check. Discuss any queries concerning the diagnostic assessment with the responsible physiotherapist.

The participant's randomization form will be completed at the end of the first Best Usual Care (BUC) treatment session by a member of the site study team. Only participants randomized to the arm of **FJI & BUC** will receive a facet joint injection.

Scheduling of the FJI appointment date will have been confirmed in writing with the participant at the end of their first BUC treatment session. If there is a change to the initial scheduled date of the

FJI, details relating to the reason for rescheduling is required to be documented in the participant's CRF, ie equipment failure, participant attended with localized infection or other reasons specified.

Prior to the study injection procedure, following normal local Trust clinical practice the investigator will obtain informed consent for the injection from the participant prior to injecting the facet joints. This is not a trial-specific informed consent process.

The investigator is required to ask and record the pain outcomes reported by participant immediately before injection (within 45-60 minutes). The question is *"On a 0 to 10 scale (0 = no pain, 10 = worst pain) what is your (the participant's) average pain reported immediately before injection?"* The answer the participant provides is required to be circled on the appropriate injection page within the CRF.

Skin cleansing with chlorhexidine 0.5% or 2% in alcohol, sterile drapes are recommended to be used.

No intravenous sedation is required.

Prone position with measures to reduce the lumbar lordosis, eg. a pillow under the abdomen.

Intravenous access.

X-ray imaging (C-arm fluoroscopy or other suitable equipment) for visualization of the joint

The dose of radiation will be adequate to visualize the joint while minimizing X-ray exposure.

Entry to the joint cleft may be indicated by X-ray appearance. Medial/lateral movement of the X-ray beam with intermittent screening to cause parallax shift may be used.

The X-ray is controlled by the operator to undertake snapshots or continuous live screening. Most practitioners use intermittent snapshots with some short periods of continuous screening. A typical procedure might involve a couple of snapshots to locate the level of the spine to be injected, followed by a short period of screening to adjust the oblique angle of the X-ray beam to display the facet joint cleft. Further snapshots would then be used to position the needle on the skin entry point, to check the alignment of the needle as it is advanced towards the joint and to confirm its position relative to the joint. A further short period of screening might then be used during which the X-ray beam is moved to and fro to utilise the parallax effect to clarify the position of the needle tip relative to the joint.

This pattern would be repeated for each joint injected.

The equipment records the cumulative exposure time. The duration of the injection procedure and cumulative exposure time is required to be recorded in the participant's case report form.

Contrast agents

For the Facet Injection Study, contrast will not be administered.

Procedure to position the needle

Following Consensus outcome and as included within the Facet Injection Study clinical trial protocol :

- No intravenous sedation required.
- Prone position with measures to reduce the lumbar lordosis, eg. a pillow under the abdomen.
- Intravenous access
- Skin cleansing with chlorhexidine 0.5% or 2% in alcohol, sterile drapes.
- Local anaesthesia at needle entry point: 1% lidocaine via 25G hypodermic needle.
- 22G (0.7mm) needle with Quincke type point guided to joint cleft.
- Entry to the joint cleft may be indicated by X-ray appearance. Medial/lateral movement of the X-ray beam with intermittent screening to cause parallax shift may be used.
- If entry to the joint has not been achieved after repositioning the needle twice, the needle will be positioned on the joint line without further attempts at capsular puncture.
- Aspiration should be negative for blood or cerebrospinal fluid.

Injection

The doctor (investigator) responsible for the injection procedure at each participating site will either be the Principal Investigator or investigator within the trial for the participating site.

The investigator responsible for the injection will prepare the injection syringe to contain 1 ml of Levobupivacaine 5mg/ml and 1ml Triamcinolone 10mg/ml in total volume; 2ml will be used for each joint.

The start time and end time of the injection will be recorded in the participant's CRF. The batch number and expiry date relating to each injectate is required to be recorded in the participant's CRF. Investigators responsible for injection are to ensure the same batch/expiry of injectate is used within the participant.

Immediately before commencement of the injection (ie 5-10 minutes before injection), the investigator is responsible for assessing the injection site for any normal or abnormal findings. The time assessed and findings are to be recorded in the participant's CRF.

Up to six facet joints (L3/L4, L4/L5, L5/S1 bilaterally) in each participant will be injected. However where on clinical assessment there is unilateral pain or involvement of only some levels, the investigator may choose to do unilateral injection, or be selective on levels injected.

The full volume, 2ml, will be injected through the spinal needle placed into each joint. Some facet joints may not be sufficiently large to take this volume of injectate meaning in practice that the injections will be intra- and peri-articular. This reflects what we believe to be current practice in the UK.

Resistance to injection may occur due to abutment of the needle bevel to a surface or due to filling of the intra-articular space. Force should not be used.

The needle should first be rotated 90° and a further attempt at injection made.

If, after two further 90° rotations resistance to injection persists or if, after successful injection of a part volume resistance develops, gentle pressure should be maintained on the plunger and the needle withdrawn gradually until resistance to injection falls.

After completion of the injection the needle is removed and a sterile dressing applied.

Post injection procedures

Immediately after completion of the injection (within 45-60 minutes post-injection), the investigator is responsible for assessing the injection site for any normal or abnormal findings. The time assessed and findings are to be recorded in the participant's CRF.

The investigator is once again required to ask and record the pain outcomes reported by participant immediately after injection (within 45-60 minutes). The question is *"On a 0 to 10 scale (0 = no pain, 10 = worst pain) what is your (the participant's) average pain reported immediately after injection?"* The answer the participant provides is required to be circled on the appropriate injection page within the CRF.

The immediate post injection advice will be provided to the participants in accordance with the current procedures of the participating study centre.

At this point the participant will have completed their trial facet joint injection procedure and the participant will continue with remaining BUC treatment sessions.

The participant's CRF is to be completed as a record of the trial injection procedure.

Drug Accountability

The clinical trial drug accountability logs for IMPs will be maintained by each site Principal Investigator, or as delegated. Accountability logs will be completed and record the unique participant ID number, date of injection, the manufacturer of IMP, batch number and expiry date for both IMPs, total volume injected, signature of investigator/IMP responsible person, and signature to confirm destruction in accordance with local destruction policy. IMP accountability will ensure traceability of the IMP administered within the trial.

IMP will be destroyed in accordance with local Trust policy.

All records will be maintained in accordance with Good Clinical Practice (GCP and in line with the Medicines for Human Use (Clinical Trials) Regulations 2004.