Barts Health NHS Trust

FACET feasibility study

PARTICIPANT INFORMATION SHEET

Title of study: A multicentre double-blind randomised controlled trial to assess the clinical- and cost-effectiveness of facet-joint injections in selected patients with non-specific low-back pain: a feasibility study

Principal Investigator: Dr Saowarat Snidvongs

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You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and healthcare professionals if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Low back pain is common in adults, and may lead to chronic disability. Lumbar facet-joints are small, paired joints in the low back that provide stability, integrity and flexibility of movement to the spine. Diseased facet-joints may cause persistent low back pain.

Although the pain may be treated with targeted facet-joint injections, there is currently no high quality or definitive clinical evidence to support their use. The National Institute for Health and Care Excellence (NICE) therefore do not currently support the use of lumbar facet-joint injections in treating low back pain due to the lack of high quality evidence.

This is a preliminary study to see whether it is feasible to conduct a larger definitive trial to assess lumbar facet-joint injections (a needle is inserted into the facet-joint and steroid injected) by comparing it to a dummy or 'sham' procedure (a needle is inserted near the facet-joint but no therapeutic substance injected).

The purpose of a feasibility study is to help researchers decide whether the intervention (lumbar facet-joint injections for low back pain) is appropriate for further testing in a larger definitive trial.

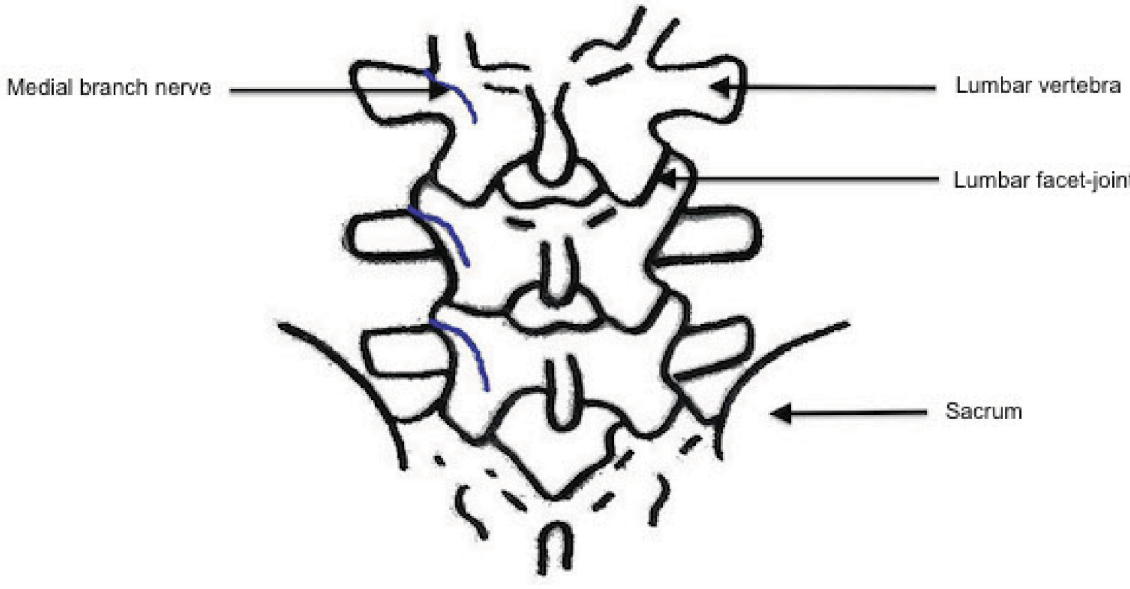


Diagram of the lower part of the vertebral column or backbone

Why have I been chosen?

You have been chosen because you have been referred to the pain clinic with low back pain of greater than three months' duration that may be of facet-joint origin. The pain has not improved despite best non-invasive care as recommended by NICE (pain education, and one or more of the following: physical education programme, acupuncture, and manual therapy).

Do I have to take part?

The decision to participate in this study is entirely up to you. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form; you are still free to change your mind and may withdraw from the study at any time and without

giving a reason. A decision to withdraw from the study at any time will not affect the standard of care that you receive now or in the future.

If you do decide to withdraw from the study, we will retain any data obtained prior to withdrawal. We will not collect any further data from you in relation to this study. You will be followed-up in the pain clinic as part of usual NHS practice.

What will happen to me if I take part?

You will first receive an appointment to have a diagnostic test for lumbar facet-joint disease. This is an injection of local anaesthetic into your low back to block the painful nerve supply to the facet-joints (medial branch nerve block). Depending on your response, you may receive a second appointment to return for either the facet-joint injections or a sham procedure. You will have an equal chance of being in either group.

The sham procedure is a 'dummy' injection near to, but not in, the facet-joint with a saline solution (no drug action). This is a necessary part of the study design, as it will enable the two procedures to be compared. You will not know whether you have been given facet-joint injections or a sham procedure, as this has been shown to be one of the best ways we have for knowing what the intervention (lumbar facet-joint injections for low back pain) really does.

An expert, who is a Consultant in Pain Medicine and the Principal Investigator at your site, will carry out all the injections. The procedures will take place in a dedicated sterile environment, such as an operating theatre in a hospital day surgery unit. You will lie on your front awake for the duration of the injections, which usually take no more than 20 to 30 minutes to complete. You will go home on the same day.

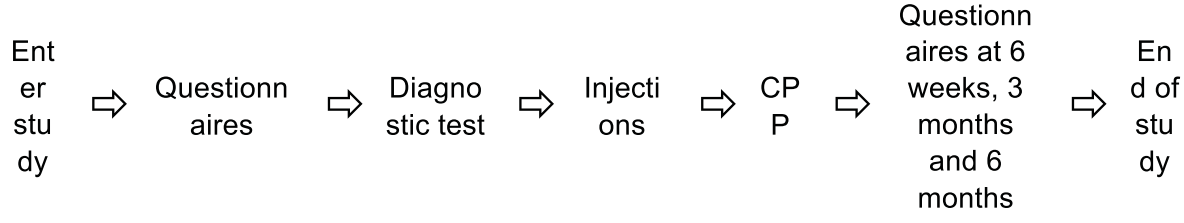
You will be invited to attend six sessions of a combined physical and psychological programme (CPP) after your injections. These will be delivered to you in small groups by a trained physiotherapist and each session will last for 90 minutes. The CPP has been recommended by NICE as a strategy to reduce pain and its impact on day-to-day life, even if the pain cannot be cured completely.

You will be required to attend six separate hospital or clinic appointments, in addition to the CPP. The first three appointments are with a Consultant in Pain Medicine and are part of routine clinical practice (initial consultation, diagnostic test, and facet-joint injections or sham procedure).

There are three follow-up visits with a research nurse after your injections, which will take place in a research clinic to complete a set of questionnaires relating to your pain and

health-related quality of life. You will complete four sets of questionnaires in total (before the injections, and 6 weeks, 3 months and 6 months after the injections).

The study will end when you complete your final set of questionnaires, six months after the injections.



What are the side effects of taking part?

The diagnostic injections and facet-joint injections are commonly performed and considered safe. The procedures may be uncomfortable but are not considered painful, and are generally well tolerated with you being awake. You may experience a brief stinging sensation when we numb your skin with a local anaesthetic. The same applies for the sham procedure group.

Minor side effects from the diagnostic injections and facet-joint injections are not uncommon and include bruising at the site of injection. Other complications include technical failure (we are unable to perform the procedure), failure to relieve pain, injury to nerves, and infection. Major complications are extremely rare.

Ionising radiation in the form of x-rays will be used in both groups – this is necessary to allow the needles to safely enter the correct space in your back. Exposure to ionising radiation increases the risk of incurring cancer in later life. The radiation dose received has been assessed by a medical physics expert and is considered to be of very low risk, comparable to about 2 months of background (environmental) radiation exposure.

What are the possible disadvantages of taking part?

There are no disadvantages in taking part in this study although it may take some time (up to an hour) to complete the questionnaires. If you are in the sham group, you are not expected to obtain any pain relief from your procedure but you will be followed-up in the pain clinic by a Consultant in Pain Medicine and offered further treatment to manage your pain as required, including facet-joint injections.

What are the possible benefits of taking part?

If you are in the treatment group and receive lumbar facet-joint injections, you may experience symptomatic relief of your low back pain. If you are in the sham group, there may be no direct benefit to you but we anticipate that the results of the study could benefit future patients with low back pain, by increasing their treatment options.

What if more information becomes available?

Sometimes during the course of a research study, new information becomes available about the treatment or medicine being studied. We will inform you of any new developments should this occur.

What happens if there is a problem?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you. If you wish to complain formally, you can do this through the NHS complaints procedure. Details of this can be obtained from the Patient Advice and Liaison Service [insert local details here].

Will my taking part be kept confidential?

Your confidentiality will be safeguarded during and after the study, with data handling, processing and storage carried out according to the Data Protection Act 1998. Any individual data will be anonymised and given a research code, and all paper data will be stored in a locked cabinet within a locked office in the Pain and Anaesthesia Research Centre at Barts Health NHS Trust in London. Electronic data will be stored on a password-protected computer accessed only by members of the research team. The data generated by the study will be entered by the research team onto an electronic database developed by the Peninsula Clinical Trials Unit, and will be analysed confidentiality at the University of Exeter by Professor Rod Taylor the study statistician.

Regulatory authorities and the study Sponsor may also look at the study data, to ensure that the study is being carried out correctly.

Involvement of your general practitioner

With your permission, your GP will be informed that you are taking part in this study. We may contact your GP prior to contacting you during the study to make sure your personal circumstances have not changed since our last contact.

What will happen to the results of the research study?

The results of the study will be entered onto a database by the research team at the Pain and Anaesthesia Research Centre at Barts Health NHS Trust, and analysed with statistical advice from the University of Exeter.

The results will be published in a report upon completion of the study, and may be made available to you on request. It is anticipated that the study will run for 21 months. You will not be identified in any report or publication.

Who is funding the research?

This study has received a grant from the National Institute for Heath Research (NIHR), which is funded through the Department of Health in the UK to improve the health and wealth of the nation through research.

Who has reviewed this study?

This study has been reviewed by the NHS Research Ethics Committee London – City & East. The National Research Ethics Service protects the rights, safety, dignity and wellbeing of research participants.

The study drugs have authorisation for use from the Medicines & Healthcare products Regulatory Agency (MHRA). The MHRA regulates medicines and medical devices in the UK.

The study has also been reviewed by the NIHR to meet the necessary scientific standards.

Contact details for further information:

If you have any general questions on taking part in research, please contact the Patient Advice and Liaison Service [insert local details here]. The research team can also be contacted directly [insert local details here].

Site Principal Investigator: [details to be inserted here]

Site lead research nurse: [details to be inserted here]

Thank you for considering taking part in this study.