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Facet-joint injections for people with persistent non-specific low back pain

Submission date
14/02/2014

Recruitment status
No longer recruiting

Registration date
27/02/2014

Overall study status
Completed

Last Edited
29/06/2017

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Facet joint injections into the back have been widely used to treat selected people with low back pain. A facet joint injection is not a cure for the cause of low back pain, but it is used to help reduce the level of pain. Unfortunately there is currently no good evidence to show that they work. For the NHS to provide these injections we need evidence to show that they work. This study aims to assess the clinical and cost effectiveness of facet joint injections.

Who can participate?
Adult patients with at least moderately troublesome low back pain present for at least six months referred by their GP (doctor) for additional treatment of back pain because simple treatments for low back pain have not worked.

What does the study involve?
Participants are randomly allocated to receive either facet joint injections and 'best usual care' physiotherapy treatment, or 'best usual care' physiotherapy treatment only. Participants are followed up at 3 months via postal questionnaires. The main questionnaire packages are completed at the start of the study and 3, 6 and 12 months later. A pain severity score is recorded daily for 35 days from seven days before first treatment session and following this weekly until the end of the study.

What are the possible benefits and risks of participating?
Facet joint injection is not a cure for the cause of low back pain, but it is used to help reduce the level of pain. All the participants will be people seeking care for back pain that is not resolving. Untreated they run the risk of developing chronic disability. Both the injection and the 'best usual care' physiotherapy treatment have the potential to improve the participant's low back pain and are treatments that they would not normally be able to access easily. The 'best usual care' physiotherapy treatment is a new programme specifically developed for this study that is focussed on improving outcome for people with pain coming from their facet joints. Although not proven to be more effective than conventional physiotherapy it is not a treatment that is available outside this study. If the injections make pain more manageable for the patient, even if only for a few weeks, then this will allow the patient to maximise the benefits of the rehabilitation programme by allowing them to regain their fitness more quickly. We cannot

promise the study will help the individual patients, but the information we get from the study may help improve the future treatment of people with low back pain. Some people find the experience beneficial and interesting. There is, however, a recognised risk of adverse events from the facet joint injection and exposure to x-rays. Patients will be exposed to low-dose radiation because x-rays are used to ensure the facet joint injection is correctly located. The actual dose received varies but typically this is a similar level of radiation exposure to the UK background level over a 6-week period. There is a very small risk of harm from taking part in the 'best usual care' physiotherapy treatment programme.

Where is the study run from?
Warwick Clinical Trials Unit (UK).

When is the study starting and how long is it expected to run for?
November 2014 to November 2015

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2014-000682-50

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 11/31/01, REGO-2013-592

Study information

Scientific Title
A mixed-methods, randomised, multicentre feasibility study to assess the clinical and cost-effectiveness of facet joint injections to best usual non-invasive care in patients with persistent non-specific low back pain

Acronym
FIS

Study objectives
In adult patients with suspected facet join pain contributing to persistent low back pain, adding the option of facet joint injections with local anaesthetic and corticosteroids to best usual non-invasive care available in the NHS is clinically and cost-effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber - Sheffield, 20/08/2014, ref: 14/YH/0161

Study design
Mixed-methods randomised multicentre feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact FIS@warwick.ac.uk to request patient information sheet

Health condition(s) or problem(s) studied
Muscoskeletal, low back pain

Interventions
Participants will be randomised to receive either facet joint injection with best usual care, or best usual care only.

Pain outcomes will be collected immediately before and after injection (intervention only), daily for up to seven days before first physiotherapy treatment session until 28 days after randomisation (including seven days after notional injection date; all injections should take place

within 21 days of randomisation), then weekly for three months post-intervention. Health utility data (EQ-5D-5L) will be collected daily for eight days around the notional injection date and then weekly from until three months after randomisation, at six and 12 months post randomisation. Other health outcomes will be collected at three months only .

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary outcome for this feasibility study is numerical rating scale for pain collected over three months following randomisation.

A package of outcome measures consistent with consensus recommendations for outcome assessment in back pain trials will be utilised. These include pain measurement, physical function, emotional function, back-related function, generic well-being, disability (social role), and satisfaction with care, patient rating of improvement and satisfaction with treatment, symptoms (pain), adverse events, participant disposition, and a modified form of the patient generated index. In this feasibility study we will assess performance of these measures and seek to reduce the questionnaire burden in the main trial.

The main questionnaire packages are completed at baseline (at study entry assessment) and follow-up (3, 6 and 12 months post randomisation). A pain severity score will be recorded daily for 35 days from seven days before first treatment session and following this weekly until the end of the study. Health utility (EQ-5D-5L) will be recorded weekly from one week prior to the first treatment session until the night before the injection appointment when we will ask participants to record it daily for eight days then weekly until the end of the study. In addition, intervention participants will record a pain severity 45-60 minutes before and after injection. Clinical data will recorded by the physiotherapists and the clinician and collected covering patients assessments, injections and involvement in the physiotherapy intervention. Note it may be necessary to increase the number of data points for the EQ-5D-5L and the pain severity score; firstly, if an injection is cancelled/rescheduled and secondly, towards the end to ensure test-retest reliability. To reduce costs and shorten time to completion of the feasibility study we will do a single cycle of postal follow-up with two postal reminders and a telephone call for primary outcomes at three months in this pilot study. In the main study we would also collect six and 12 month data. We do not anticipate any additional benefit from collection of long-term follow-up data in this pilot.

Secondary outcome measures
As a second primary outcome focused on back pain related disability we will use the Roland Morris Disability Questionnaire at three months, six and 12 months collected using a postal questionnaire

Overall study start date
01/11/2014

Completion date
01/11/2015

Eligibility

Key inclusion criteria
Current inclusion criteria as of 22/09/2014:
1. The patient is willing to comply with the trial procedures and signed and dated informed consent is obtained
2. The patient is aged >18 with at least moderately troublesome low back pain present for at least six months
3. The patient reports low back pain as their predominant musculoskeletal pain
4. The patient has undergone therapist-delivered treatment for low back pain in the preceding six months prior to inclusion
5. The patient meets clinical criteria for possible facet joint pain when there is no radicular symptoms (defined as pain radiating below the knee) and no sacro-iliac joint pain elicited using a pain provocation test and increased pain unilaterally, bilaterally on lumbar para-spinal palpation, and increased low back pain on one or more of the following: extension (more than flexion), rotation, extension/side flexion, extension/rotation
6. The patient is able to manage text messaging, or an alternative means of daily data collection (paper-based diary)
7. The patient is fluent in written and spoken English

Previous inclusion criteria:
1.The patient is able and willing to comply with the trial procedures and signed and dated informed consent is obtained
2.The patient is >18 with at least moderately troublesome low back pain present for at least six months
3.The patient has undergone therapist-delivered treatment for low back pain in the preceding six months prior to inclusion
4.The patient meets clinical criteria for possible facet joint pain
5.The patient is able to manage text messaging, or an alternative means of daily data collection (paper based diary)
6.The patient is fluent in written and spoken English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
Current exclusion criteria as of 22/09/2014:
1. The patient is unable to attend for randomised treatment, or other circumstances that would significantly decrease the chance of obtaining reliable data, achieving trial objectives or

completing the trial and follow-up assessments or is considered unsuitable to participate in the trial by an investigator
2. The patient is unable/unwilling to undergo injections
3. The patient has used oral corticosteroids or had a corticosteroid injection in the preceding three months.
4. The patient is has an underlying serious psychiatric or psychological disorder that precludes participation in either intervention
5. The patient has previously undergone spinal injections
6. The patient is has previously undergone spinal surgery
7. The patient has a contraindication to facet joint injections; for example, a serious co-morbidity (e.g., severe COPD, poorly controlled diabetes), malignancy, infection, inflammatory disorder, or fracture; or is taking anti-coagulant medication
8. The patient has a known allergy to the constituents of the planned injections
9. The patient is pregnant, or suspected pregnancy
10. The patient was previously randomised in this trial
11. The patient is currently participating in another clinical trial (with an unregistered medicinal product), or less than 90 days have passed since completing participation in such a trial

Previous exclusion criteria:
1.The patient is unable to attend for randomised treatment, or other circumstances that would significantly decrease the chance of obtaining reliable data, achieving study objectives or completing the study and follow up assessments or is considered unsuitable to participate in the study by an investigator.
2.The patient is unable/unwilling to undergo injections.
3.The patient has an underlying serious psychiatric or psychological disorder that precludes participation in either intervention.
4.The patient has a contraindication to facet joint injections (eg, serious co-morbidity, previous spinal surgery, or taking anti-coagulants).
5.The patient has a known allergy to the constituents of the planned injections.
6.The patient is pregnant or breast feeding.
7.The patient was previously randomised in this trial.
8.The patient is currently participating in another clinical trial (with an unregistered medicinal product), or less than 90 days have passed since completing participation in such a trial.

Date of first enrolment
01/11/2014

Date of final enrolment
01/04/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Warwick Clinical Trials Unit
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University Hospitals Coventry & Warwickshire NHS Trust (UK)

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University Hospital
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/025n38288

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2017		Yes	No
HRA research summary			26/07/2023	No	No