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Assessing the clinical- and cost-effectiveness of facet-joint injections in selected patients with non-specific low back pain

Submission date
21/11/2013

Recruitment status
No longer recruiting

Registration date
03/01/2014

Overall study status
Completed

Last Edited
15/02/2018

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
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 lead to persistent low back pain. A number of treatment options are available to treat lumbar facet-joint pain, with the aim of restoring function and achieving a good quality of life. These include medication, physical therapy, injection of therapeutic substances into the back (such as facet-joint injections), and surgery. However, at present, there is insufficient high-quality evidence to support the use of lumbar facet-joint injection for non-specific low back pain of less than 12 months duration, and hence The National Institute of Health and Clinical Excellence (NICE) did not approve their use in their 2009 publication to cover the early treatment and management of persistent low back pain.

Who can participate?
Patients aged 18 to 70 years with low back pain of greater than three months duration.

What does the study involve?
Patients will receive diagnostic injections (medial branch nerve blocks); those with a positive response will be randomly allocated to receive either facet-joint injections or a sham procedure. The patients will then receive a combined physical and psychological programme, involving a cognitive behavioural approach and exercise. This has been recommended by NICE as a strategy to reduce pain and its impact on the persons day -to-day life, even if the pain cannot be cured completely.

What are the possible benefits and risks of participating?
If successful this study will demonstrate that we are able to standardise the methods for facet-joint injection and sham procedure, and that the proposed study design is deemed acceptable by patients and clinicians. There are no obvious risks to participating, although there can be procedure-related side effects. These include flare up, pain at the site of injection, and redness in the area.

Where is the study run from?
The study will be conducted in three hospital-based pain medicine centres: Barts Health NHS Trust (until April 2012, Barts and The London NHS Trust), Basildon and Thurrock University Hospitals NHS Foundation Trust, and The Walton Centre NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
We expect to start the study in April 2014 and we anticipate that the project will take a total of 21 months to complete.

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Professor Richard Langford
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PARC_HTA_11/31/02

Study information

Scientific Title

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

Study objectives
The aim of this study is to assess the feasibility of conducting a definitive trial to evaluate the clinical- and cost-effectiveness of facet-joint injections (FJIs) compared to a sham procedure, in patients with non-specific low back pain of more than three months duration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study will be reviewed by a Research Ethics Committee, to ensure that the rights, safety, dignity and well-being of study participants are protected. A copy of the proposed informed consent form will be reviewed with the study protocol. The NETSCC will be informed once a specific NRES committee has been appointed. We will apply for ethical review through the centralised National Research Ethics Service (NRES) system and commence work on the application on approval of an agreed protocol and agreement to fund the study.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Low back pain

Interventions
Patients will be recruited from pain clinics at the three participating NHS centres and their associated community-based pain clinics. Patients will be referred by their general practitioners with low back pain requiring further specialist assessment, for reasons such as uncertain diagnosis, failure of conservative treatment or expectation of therapeutic interventions. We will recruit a total of 150 patients, of whom 60 (40%) are expected to have a positive diagnostic test for facet-joint disease, and these 60 patients will be randomly and equally allocated to receive one of the following two interventions:

1. Facet-joint injections of local anaesthetic and steroid plus a combined physiotherapy and psychology (CPP) programme
2. A sham (placebo) procedure plus a CPP programme

FJIs, the sham procedures and diagnostic tests will be performed in day surgery units at each of the three main centres. They will be carried out only by appropriately qualified members of the research team (Fellows of the Faculty of Pain Medicine of the Royal College of Anaesthetists), adhering to strict aseptic conditions and following local theatre protocols with regards to admission and discharge criteria.

Intervention Type
Mixed

Primary outcome measure
To assess the eligibility criteria, recruitment and retention of patients in the two treatment arms (FJI versus sham procedure)

Secondary outcome measures
1. To assess the feasibility and acceptability of the two treatment arms from the point of view of patients and their pain teams
2. To assess the feasibility of the proposed definitive trial design including:
2.1. Testing of randomisation and blinding procedures
2.2. Development of an appropriate active and sham procedure for FJIs
2.3. Assessment of the consistency of the trial sites to deliver the combined physical and psychological programme
2.4. Ability to collect the outcomes proposed for the main trial (pain, functioning, health-related quality of life, anxiety and depression, healthcare resource utilisation, complications and adverse events)
3. To estimate outcome standard deviation to inform the power calculation for a definitive trial
4. To finalise the protocol design, statistical plan, number of centres required and study duration of the definitive trial

Overall study start date
01/04/2014

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. Patients aged 18 to 70 years attending pain clinics identified during routine clinical assessment of nonspecific low back pain
2. Low back pain of greater than three months duration
3. Average pain intensity score of 4/10 or more in the seven days preceding recruitment despite NICE-recommended treatment
4. Dominantly paraspinal (not midline) tenderness at two bilateral lumbar levels
5. At least two components of NICE-recommended best non-invasive care completed, including education and one of a physical exercise programme, acupuncture and manual therapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Patient refusal
2. More than four painful lumbar facet-joints
3. Patient has not completed at least two components of NICE-recommended best non-invasive care
4. 'Red flag' signs
5. Hypersensitivity to study medications or X-ray contrast medium
6. Radicular pain
7. Dominantly midline tenderness over the lumbar spine
8. Any other dominant pain
9. Any major systemic disease or mental health illness that may affect the patients pain, disability and/or their ability to exercise and rehabilitate
10. Any active neoplastic disease, including primary or secondary neoplasm
11. Pregnant or breastfeeding patients
12. Previous lumbar facet-joint injections
13. Previous lumbar spinal surgery
14. Patients with morbid obesity (body mass index of 35 or greater)
15. Major trauma or infection to the lumbar spine
16. Participation in another clinical trial in the past 30 days
17. Patients unable to commit to the six-month study duration
18. Patients involved in legal actions or employment tribunals related to their low back pain
19. Patients with a history of substance abuse

Date of first enrolment
01/04/2014

Date of final enrolment
31/03/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Barts and the London NHS Trust/Queen Mary College, University of London
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Sponsor information

Organisation
NIHR Health Technology Assessment Programme - HTA (UK)

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Sponsor type
Government

Website
http://www.nets.nihr.ac.uk/programmes/hta

ROR
https://ror.org/0187kwz08

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	01/12/2017		Yes	No