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Percutaneous RadioFrequency treatment for FACET joint pain

Submission date
07/07/2013

Recruitment status
No longer recruiting

Registration date
19/07/2013

Overall study status
Completed

Last Edited
25/06/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Pain in the facet joint of the spine remains a misunderstood and an improperly treated medical condition. Research proposes that facet joints are responsible for a significant amount of low back pain. There are difficulties in diagnosing facet joint pain using various techniques. Previous studies concluded that a technique called radiofrequency lumbar facet joint denervation gives a significant pain relief in a select group of patients with chronic low back pain, both on a short-term and a long-term basis. We are investigating whether a technique called percutaneous radiofrequency heat lesion can bring significant and long-lasting pain relief. A cost analysis will also be performed for each individual treatment as well as for the complete healthcare system. The results will be used for further studies.

Who can participate?
Patients aged 18 or older and with a physical investigation suggestive of facet joint pain can participate in the study.

What does the study involve?
Patients are randomly allocated to one of two groups: group 1 (treatment group) undergoes a procedure that includes percutaneous radiofrequency heat lesion treatment, while group 2 (sham-operated group) undergoes the same procedure as in group 1 except without the radiofrequency heat lesion treatment. Patients belonging to group 2 will receive the radiofrequency heat lesion treatment after 3 months if there is no significant improvement in the pain. Both groups will be followed up.

What are the possible benefits and risks of participating?
This procedure is associated with an overall 1.0% incidence of minor complications, consisting of local pain lasting more than 2 weeks and nervous pain lasting less than 2 weeks. No major complications seem to be found, but recently a case report was presented concerning death following lumbar facet joint injection due to infection.

Where is the study run from?
This study is run from Lievensberg Hospital, Bergen op Zoom, The Netherlands and Franciscus hospital, Roosendaal, The Netherlands.

When is the study starting and how long is it expected to run for?
The study started in March 2012 and is expected to run for 3 years.

Who is funding the study?
Centre for Pain Medicine, Erasmus University MC, Rotterdam, The Netherlands.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL36850.078.11

Study information

Scientific Title
Randomised sham-controlled double-blind multicenter clinical trials to evaluate the percutaneous radiofrequency treatment for facet joint pain

Acronym
RF FACET

Study objectives
Investigates the value of percutaneous radiofrequency heat lesion, applied to the medial branch of the primary dorsal ramus; more specifically it tries to determine if a significant and long

lasting pain reduction can be obtained as compared to a sham-operated group. In addition to the primary objective a cost analysis will be performed for each individual treatment as well as for the complete healthcare system. The results will be used for further studies concerning intervention in spine related pain disorders.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval has been granted by the Medical Ethics Committee (Medisch Ethische Toetsings Commissie) (METC) Erasmus MC, Rotterdam, The Netherlands on february 7, 2012 (multicenter approval on july 10, 2012), reference number MEC-2011-248.

Study design
Randomised sham-controlled double-blind multicenter clinical trial

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 use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Spine related pain disorders

Interventions
Patients with chronic low back pain in whom anamnesis, physical investigation and additional investigations point towards a facet joint problem first receive a diagnostic facet joint medial branch block on three adjecent levels (according to the innervation of the lumbar facet joints):

Facet joint medial branch diagnostic injection:
The medial branch of the affected lumbar facet joint is infiltrated, together with the medial branch of the adjecent cranial and caudal lumbar facet joint. The diagnostic injection is performed fluoroscopically and by means of three Sluijter-Mehta Kit (SMK) needles (Cotop® via Neurotherm®, Wilmington, Massachusetts, United States) with an overall length of 10 cm. Local anesthesia with 1 mL lidocaine 2% per level is given for skin infiltration. Each medial branch is infiltrated with 0,25 mL lidocaine 2%. The results of the diagnostic injections are rated according to Ostelo et al. (Ostelo, 2008), in which a positive result is obtained with a reduction in NRS of 2 or more on 10. Patients with a reduction in NRS of less than 2 on 10 drop out of the study.

When patients are candidates for the RCT they are randomized in two study groups: Continuous radiofrequency heat lesion of the medial branch versus sham:
Group 1 (treatment group): skin infiltration with 1 mL lidocaine 2% per level, percutaneous radiofrequency heat lesion (80° C during 60 sec. per level) with the NT2000 laesion generator (Neurotherm®, Wilmington, Massachusetts, United States) at the medial branches of the primary dorsal rami on three adjecent levels after local anesthesia with 0,5 mL lidocaine 2% per level
Group 2 (sham-operated group) same procedure as in treatment group except for radiofrequency heat lesion). This is followed with graded activity and follow up for both groups

A crossover is provided for the sham-operated group after three months is no significant pain relief is obtained. The results of the crossover group will be analyzed separately, as well as compared with those who received the actual treatment in the first case.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Pain reduction (NRS) measured on the day of first consultation, 1, 3, 6 and 12 months after the treatment

Secondary outcome measures
1. Pain: Chronic Pain Acceptance Questionnaire (CPAQ), Four-Dimensional Symptom Questionnaire (4DSQ), Multidimensional Pain Inventory (MPI-DLV) measured on the day of first consultation, 3 and 12 months after the treatment
2. Disability: Oswestry Disability Index (ODI) measured on the day of first consultation, 3 and 12 months after the treatment
3. Generic health status: Rand-36 measured on the day of first consultation, 3 and 12 months after the treatment
4. Kinesiophobia: Tampa Scale for Kinesiophobia (TSK) measured on the day of first consultation, 3 and 12 months after the treatment
5. Coping: Pain Coping Inventory (PCI), Pain Cognition List (PCL-2003) measured on the day of first consultation, 3 and 12 months after the treatment
6. Costs of intervention

Overall study start date
01/03/2012

Completion date
01/03/2015

Eligibility

Key inclusion criteria
1. Age 18 years or older
2. Anamnesis and physical investigation suggestive of facet joint pain on lumbar level
3. Decrease in Numeric Rating Scale (NRS) of 2 or more / 10 on diagnostic facet joint medial branch block

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Presence of red flags: possible fracture (major trauma, minor trauma in elderly or osteoporotic), possible tumor or infection (age >50 or <20, history of cancer, constitutional symptoms (fever, chills, weight loss), recent bacterial infection, IV drug abuse, immunosuppression, pain worsening at night or when supine), possible significant neurological deficit (severe or progressive sensory alteration or weakness, bladder or bowel dysfunction, evidence of neurological deficit (in legs or perineum in the case of low back pain)
2. Lumboradicular syndrome
3. Aspecific low back pain
4. Corpus vertebrae problem
5. Progressive neurological defecits
6. Major psychiatric disorder (according to psychiatrists opinion)
7. Anticoagulation cannot be stopped
8. Active infection
9. Pain in other parts of the body that is more severe
10. Allergies to any medication used in the study
11. Pregnancy
12. Communication (language) difficulties (according to physicians opinion)

Date of first enrolment
01/03/2012

Date of final enrolment
01/03/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
Multidisciplinary pain centre
Bergen op Zoom
Netherlands
4624 VT

Sponsor information

Organisation
Erasmus University Medical Centre (MC) (Netherlands)

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Sponsor type
University/education

ROR
https://ror.org/018906e22

Funder(s)

Funder type
University/education

Funder Name
Centre for Pain Medicine, Erasmus University MC, Rotterdam, Netherlands

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	01/11/2016	25/06/2020	Yes	No