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Percutaneous RadioFrequency treatment for DISCogenic pain at the communicating ramus

Submission date
05/07/2013

Recruitment status
No longer recruiting

Registration date
12/07/2013

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
Chronic low back pain is the biggest factor limiting activity in young adults under the age of 45. Discogenic pathology (a disorder originating in or from an intervertebral disc in the spine) is estimated to be responsible for chronic low back pain in between 7% and 39% of patients in several studies. Degenerative changes (gradual loss of the normal structure and function of the spine over time) can result in pain. Discogenic low back pain problems require the presence of free nerve endings and inflammation; a high concentration of nerves and vessels is present in the outer third of the annulus and the endplate areas (parts of spine), likely the sites where pain is produced. Several treatment options have been developed for reducing pain. There is weak evidence for intradiscal electrothermic therapy (IDET), radiofrequency annuloplasty, thoracic duct drainage (TDD) and radiofrequency denervation of the ramus communicans nerve.
The aim of this study is to investigate the value of radiofrequency heat lesion applied through the skin to the ramus communicans nerve and to determine if a significant and long-lasting pain reduction can be obtained as compared to a sham (dummy)-operated group. In addition to the above, 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.

Who can participate?
Patients aged 18 or more with a case history and physical investigation suggestive of discogenic pain.

What does the study involve?
Group 1 (treatment group): percutaneous radiofrequency heat lesion (80°C, 60 sec) at the ramus communicans nerve
Group 2 (sham-operated group): same procedure as in group 1 except radiofrequency heat lesion.

What are the possible benefits and risks of participating?
Minimally invasive treatments provide alternatives for discogenic pain with the appeal of cost-effectiveness and, possibly, fewer long-term side effects. No major complications are reported.

Where is the study 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?
Start date March 1, 2012; end date March 1, 2015.

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL36869.078.11

Study information

Scientific Title
Randomised sham-controlled double-blind multicenter clinical trial to evaluate the percutaneous radiofrequency treatment for discogenic pain at the communicating ramus

Acronym
RF DISC

Study objectives
Investigate the value of percutaneous radiofrequency heat lesion applied to the ramus communicans, more specifically, trying to determine if a significant and long lasting pain reduction can be obtained when compared to a sham-operated group. In addition to above, 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-2011-242.

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

Primary study design
Interventional

Study type(s)
Treatment

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 discogenic problem first receive a diagnostic ramus communicans block.

Ramus communicans diagnostic injection:
The ramus communicans of the affected lumbar disc is infiltrated. The diagnostic injection is performed fluoroscopically and by means of a Sluijter-Mehta Kit (SMK) needle (Cotop® via Neurotherm®, Wilmington, Massachusetts, United States) with an overall length of 15 cm. Local anesthesia with 1 mL lidocaine 2% is given for skin infiltration. The ramus communicans 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 randomised in two study groups:

(Continuous) radiofrequency [(C)RF] heat lesion of the ramus communicans versus sham:
Group 1 (treatment group): skin infiltration with 1 mL lidocaine 2%, percutaneous RF heat lesion (80 degrees Celcius during 60 sec. per level) with the NT2000 laesion generator (Neurotherm®, Wilmington, Massachusetts, United States) at the ramus communicans of the affected lumbar disc after local anesthesia with 0,5 mL lidocaine 2%
Group 2: sham-operated group (same procedure as in treatment group except for RF 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(s)
Pain reduction (NRS) measured at baseline,1, 3, 6 and 12 months.

Key secondary outcome(s))
1. Pain: Chronic Pain Acceptance Questionnaire (CPAQ) , Four-Dimensional Symptom Questionnaire (4DSQ), Multidimensional Pain Inventory (MPI-DLV) measured at baseline, 3 and 12 months
2. Disability: Oswestry Disability Index (ODI) measured at baseline, 3 and 12 months
3. Generic health status: Rand-36 measured at baseline, 3 and 12 months
4. Kinesiophobia: Tampa Scale for Kinesiophobia (TSK) measured at baseline, 3 and 12 months
5. Coping: Pain Coping Inventory (PCI), Pain Cognition List (PCL-2003) measured at baseline, 3 and 12 months
6. Costs of intervention

Completion date
01/03/2015

Eligibility

Key inclusion criteria
1. Age 18 years or older
2. Anamnesis and physical investigation suggestive of discogenic pain on lumbar level
3. Decrease in numeric rating scale (NRS) of 2 or more / 10 on diagnostic ramus communicans block

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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 deficits
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)

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

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	01/03/2017	25/06/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes