A randomized, controlled, single-blinded, multicenter clinical trial to evaluate the percutaneous radiofrequency treatment of discogenic pain at the ramus communicans versus a sham-operated group

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Investigate the value of percutaneous radiofrequency heat lesion applied to the ramus communicans; more specifically try to determine if a significant and long lasting pain reduction can be obtained as compared to a sham-operated group. In addition...

Ethical review	Approved WMO
Status	Pending
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Interventional

Summary

ID

NL-OMON38048

Source
ToetsingOnline

Brief title
Intervention for discogenic pain

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
- Nervous system, skull and spine therapeutic procedures

Synonym
Disc, Discogenic

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Disc, Discogenic, Pain, RCT

Outcome measures

Primary outcome

Pain reduction (NRS).

Secondary outcome

Pain: Chronic Pain Acceptance Questionnaire (CPAQ), Four-Dimensional Symptom

Questionnaire (4DSQ), Multidimensional Pain Inventory (MPI-DLV);

Disability: Oswestry Disability Index (ODI);

Generic health status: Rand-36;

Kinesiophobia: Tampa Scale for Kinesiophobia (TSK);

Coping: Pain Coping Inventory (PCI), Pain Cognition List (PCL-2003).

Costs of intervention.

Study description

Background summary

Chronic low back pain is the biggest factor limiting activity in young adults under the age of 45. Discogenic pathology is estimated to be responsible for chronic low back pain between 7% and 39% in several studies. Degenerative changes can give rise to the existence of 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 adreas, likely the sites where pain is produced. Several treatment options have been developped for providing a significant pain reduction, evidence (weak) does exist for IDET, radiofrequency annuloplasty, TDD and radiofrequency denervation of the ramus communicans.

Study objective

Investigate the value of percutaneous radiofrequency heat lesion applied to the ramus communicans; more specifically try to determine if a significant and long lasting pain reduction can be obtained as compared to a sham-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.

Study design

Randomised, controlled, single-blinded, multicenter clinical trial.

Intervention

Group 1 (treatment group): percutaneous RF heat lesion (80°C, 60 sec) at the ramus communicans; group 2 sham-operated group (same procedure as in group 1 except RF heat lesion). Both groups will receive graded activity.

Study burden and risks

Minimally invasive treatments provide alternatives for discogenic pain with the appeal of cost-effectiveness and, possibly, less long-term side effects. No major complications are reported with treatment of the ramus communicans.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Age 18 years or older
2) Anamnesis and physical investigation suggestive of discogenic pain on lumbar level
3) Decrease in NRS of 2 or more / 10 on diagnostic ramus communicans block

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)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2011
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Generic name:	SMK needle
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-02-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-07-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL36869.078.11