ISRCTN45914408 https://doi.org/10.1186/ISRCTN45914408

Percutaneous radiofrequency treatment for sacroiliac joint pain

Submission date
07/07/2013

Recruitment status
No longer recruiting

Registration date
15/07/2013

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
In the past, research have appeared about the identification and treatment of sacroiliac (SI) joint pain (low back pain). The SI joint has been shown to be involved in 10% to 38% of the patients with chronic low back pain. For identifying SI joint problems, an injection into the joint is still being used. One of the most promising treatments is the use of radio frequency (RF) current (electricity). Several studies describe a good success rate with this kind of treatment. This study aims to find out the value of percutaneous radiofrequency heat lesion (application of heat produced by electric current through the skin) and to find out if a significant and long lasting pain reduction can be obtained as compared to when RF heat lesion was not given. In addition to the above, a cost of an individual treatment as well as cost to the complete healthcare system will be analyzed. The results will be used for further studies.

Who can participate?
Patients aged 18 or more with low back pain can participate in the study.

What does the study involve?
Patients will be randomly allocated to one of two groups. One group receives RF heat lesion treatment and the other group (control)receives treatment procedure that does not have RF heat lesion treatment. After three months, control group patients will receive RF heat lesion treatment. These results are compared separately.

What are the possible benefits and risks of participating?
This procedure is associated with a very small incidence of minor complications. No major complications were found in this procedure.

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 until March 2015.

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

Who is the main contact?
Dr C.W.J. van Tilburg
vtilburg@ziggo.nl

Contact information

Type(s)
Scientific

Contact name
Dr Cornelis Wilhelmus Jacobus van Tilburg

Contact details
Multidisciplinary pain centre
Lievensberg hospital
Boerhaaveplein 1
Bergen op Zoom
Netherlands
4624 VT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL36871.078.11

Study information

Scientific Title
Randomised sham-controlled double-blind multicenter clinical trial to evaluate the percutaneous radiofrequency treatment of sacroiliac joint pain

Acronym
RF SIJ

Study objectives
Investigate the value of percutaneous radiofrequency heat lesion, applied to dorsal ramus of L5 and lateral branches of S1, S2, S3 and S4 nerve roots, 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 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-2011-244.

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 sacroiliac (SI) joint problem first receive a diagnostic SI joint block:

Sacroiliac joint diagnostic injection:
The diagnostic injection is performed fluoroscopically and by means of one Sluijter-Mehta Kit (SMK) needle (Cotop® via Neurotherm®, Wilmington, Massachusetts, United States) with an overall length of 10 cm. Local anesthesia with 1 mL lidocaine 2% is given for skin infiltration. Correct needle position is confirmed with contrast agent (iohexol (Omnipaque®) 240 mg/dL). The SI joint is infiltrated with 3 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:
Radiofrequency heat lesion of the posterior ramus of L5 and lateral branches of S1, S2, S3 and S4 with the Simplicity© III probe versus sham:
Group 1 (treatment group): skin infiltration with 1 mL lidocaine 2% per level, infiltration of the course of the Simplicity© III needle with 10 mL lidocaine 2%, percutaneous radiofrequency heat lesion (85°C, each step 1.5 minutes) with the NT2000 lesion generator (Neurotherm®,

Wilmington, Massachusetts, United States) at the lateral branches of S1, S2, S3 and S4 nerve roots, percutaneous heat lesion (85°C for 90 seconds, same laesion generator) of the L5 dorsal root primary ramus.
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 [Numerical Rating Scale (NRS)] measured on the day of first consultation, 1, 3, 6 and 12 months after 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 treatment
2. Disability: Oswestry Disability Index (ODI) measured on the day of first consultation, 3 and 12 months after treatment
3. Generic health status: Rand-36 measured on the day of first consultation, 3 and 12 months after treatment
4. Kinesiophobia: Tampa Scale for Kinesiophobia (TSK) measured on the day of first consultation, 3 and 12 months after treatment
5. Coping: Pain Coping Inventory (PCI), Pain Cognition List (PCL-2003) measured on the day of first consultation, 3 and 12 months after 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 SI joint pain
3. Decrease in NRS of 2 or more / 10 on diagnostic SI joint block

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
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, intravenous (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)

Sponsor details
c/o F.J.P.M. Huygen
Centre for Pain Medicine
's-Gravendijkwal 230
Rotterdam
Netherlands
3015 CE

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