ISRCTN46778702 https://doi.org/10.1186/ISRCTN46778702

Pilot study on the effect of Intradiscal Pulsed RadioFrequency treatment for the management of low back pain and ischialgia of discogenic origin

Submission date
23/01/2011

Recruitment status
No longer recruiting

Registration date
23/02/2011

Overall study status
Completed

Last Edited
22/02/2013

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Olav Rohof

Contact details
Jacob Catslaan 11
Eindhoven
Netherlands
5611 LP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PRFDisc-2007/01

Study information

Scientific Title
Pilot study in patients with Degenerative Disc Disease and concordant pain with discography and the effect of percutaneous intradiscal Pulsed RadioFrequency treatment

Acronym
Intradiscal PRF for DDD

Study objectives
Degenerative intervertebral disc may be the cause of low back pain in 45% of the cases. The innervation is deeper and more widespread in the degenerative disc than in the normal disc; some fibres even penetrate the nucleus pulposus. Discogenic pain may be caused by disc herniation, which depending on the degree of herniation may resolve spontaneously within weeks to months. When herniation is however more pronounced, pressure can be exerted on the adjacent nerve (root), moreover the nucleus pulposus material that is spilled on the nerve (root) and surrounding tissues may give rise to inflammation that in turn results in radicular pain. More severe disc degeneration consists of dehydration of the annulus fibrosus, loss of disc height and hence loss of elasticity and shock absorbing potential. All or some of these mechanisms may cause a "chemically or mechanically" sensitised disc. When conservative treatment, consisting of adequate use of pain medication and physical therapy fail to provide satisfactory pain relief or cause intolerable side effects, an interventional approach may be considered.

Prior to proposing interventional pain management techniques to the patient a comprehensive diagnostic work-up is mandatory. The history and clinical examination will provide a working diagnosis of the involvement of one or more intervertebral discs. Red flags, such as tumor, infection, fracture, spondylolisthesis, etc., will be excluded mostly by use of plain radiography. The disc pathology can be confirmed by magnetic resonance imaging and the causative level is confirmed by means of provocative discography. Following the different diagnostic steps helps in establishing the diagnosis of degenerative disc disease as cause of low back pain.

The management of degenerative disc disease may consist of heating the annulus fibrosus by means of radiofrequency current, in the objective to coagulate the collagen and destroying the nerve endings in the annulus fibrosus. Several devices have been developed to achieve adequate tissue heating. The published results of those treatments are variable and no clear conclusion on the efficacy can be drawn. Moreover using those devices requires a minimal residual disc height of 50%, and their application requires experience and breakage of the device and other severe complications have been reported. Because of the flexible nature of those devices they are designed for single use. The devices are not reimbursed by the health insurances which makes the procedure expensive for the patient.

Spine surgery may be considered for patients suffering intractable pain due to a degenerative disc. Discectomy can be considered but the most frequently used technique is the spondylodesis, that aims at decompression of the disc and fixation of the vertebral segment. The major drawback of arthrodesis is the resulting rigidity of the spine at the level where it is performed. The other orthopedic therapeutic option is placing of a disc prosthesis, but also in this technique severe complications have been described and result are equivocal.

Each treatment option that may provide clinically relevant pain relief [2 points on a 10-point Visual Analogue Scale (VAS) scale or 30 % pain reduction] for a relatively long period (i.e. longer

than 6 months) in an appreciable proportion of patients and is well tolerated is worth further investigating.

Pulsed radiofrequency treatment has been reported to induce changes in the pain conduction when applied close to a nerve. However, more recently casuistic on the potential beneficial effect of PRF applied in a small or even large joint was published.

In earlier study we found a beneficial effect of applying pulsed radiofrequency by means of two electrodes placed in the annulus fibrosus. We assumed that a PRF treatment in the nucleus would change the conductivity of nerve endings that have been sprouting into the nucleus due to disc degeneration and thus provide a clinically relevant pain reduction. The application of the electric field of PRF in the disc may also induce healing processes involving the activation of the immune system, thus reducing the inflammation process of chronic pain.

We assessed the data of 76 patients treated with PRF in the nucleus in order to be able to judge if a controlled trial is justified.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval was sought from the Ethics Committee of the Orbis Medical Centre. However, because no novel treatment was used no official approval was needed.

Study design
Prospective longitudinal observational trial

Primary study design
Observational

Secondary study design
Cross-section survey

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet (Dutch only)

Health condition(s) or problem(s) studied
Discogenic low back pain

Interventions
Prior to inclusion in the study patients undergo extensive clinical examination. Attention for pain on flexion and deflexion and the odd biphasic deflexion. Tenderness when pressure is applied on the processus spinosus, the radiation pattern is indicative for the causative disc level. Confirmation of this level is sought by means of discography (at 3 levels). Baseline pain VAS

score (on a 10 point numeric scale; 0 = no pain and 10 = the worst imaginable pain) is noted and the analgesic use. The causative level is treated with pulsed radiofrequency. The electrode is placed in the nucleus. Pulsed radiofrequency current is applied during 15 minutes. At 3 months and 12 months VAS pain score and analgesic consumption is documented. Cross-over to surgery is noted.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Pain reduction measured on a 10-point VAS score (0 = no pain, 10 = unbearable pain) at 3 months and at 12 months

Secondary outcome measures
1. Side effects and complications
2. Potential effect of additional treatment after the 3 month evaluation
3. Result measurement of combined treatment at 12 months follow up

Overall study start date
01/03/2008

Completion date
01/02/2011

Eligibility

Key inclusion criteria
1. Patients greater than 18 years old, either sex
2. Low back pain of greater than or equal to 6 months duration
3. Pharmacological treatment was used at appropriate doses for an accurate period of time without satisfactory pain relief and/or intolerable side effects
4. Physical therapy was used for a sufficiently long period of time (at least 6 weeks) to judge a potential effect
5. History and clinical examination is indicative for discogenic pain
6. Magnetic resonance imaging (MRI) confirms disc degeneration
7. Positive provocative discography

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
50 participants

Key exclusion criteria
1. Patients less than 18 years
2. Infection at the needle insertion site
3. Major coagulation disorders
4. Red flags: tumour, infection, fracture, spondylolisthesis grade 3, etc.

Date of first enrolment
01/03/2008

Date of final enrolment
01/02/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Jacob Catslaan 11
Eindhoven
Netherlands
5611 LP

Sponsor information

Organisation
Orbis Medical Centre Sittard-Geleen (Netherlands)

Sponsor details
Dr. H. van der Hoffplein 1
Sittard-Geleen
Netherlands
6162 BG

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Industry

Funder Name
NeuroTherm (Netherlands) - provided support for writing of the manuscript

Funder Name
All other costs are met either by the investigator or through regular patient management.

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	01/06/2012		Yes	No