

Radiofrequency denervation of the sacroiliac joint and the additive value of diagnostic tests

Published: 13-02-2007

Last updated: 20-05-2024

1.) To determine the diagnostic value of a intra-articular injection with local anesthetics in the SIJ followed by RF SIJ denervation.2.) To determine the diagnostic value of a set of 5 SI provocation tests at examination, of with at least 3 are...

Ethical review	Not approved
Status	Will not start
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON30438

Source

ToetsingOnline

Brief title

Radiofrequency denervation of the sacroiliac joint

Condition

- Joint disorders

Synonym

low back pain, Sacroiliac joint related pain

Research involving

Human

Sponsors and support

Primary sponsor: Gelre Ziekenhuizen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: diagnostic blocks, provocation tests, Radiofrequency denervation, sacroiliac joint

Outcome measures

Primary outcome

pain reduction

Secondary outcome

increase of daily activities.

Study description

Background summary

Chronic low back pain (CLBP) is a frequently occurring disease with major impact for patients and society. The life-time prevalence of low back pain is 70-80%. In recent years there is increasing evidence that the sacroiliac joint (SIJ) is (in part) a source in a subgroup of CLBP patients. The prevalence of SI joint pain in patients with CLBP is estimated 13-30%. The diagnosis *SIJ related pain* is difficult to establish.

The gold standard for diagnosing SI joint related pain in patients with CLBP is the intra-articular injection with local anesthetic. If positive a radiofrequency denervation procedure of the SI joint will be done. Recently, 2 studies showed a good correlation between the intra-articular injection and a multitest regime of SI provocation tests.

For the treatment of SI related pain minimal invasive techniques, like radiofrequency (RF) denervation, are used. Usually, prior to RF procedures, a diagnostic intra-articular injection with local anesthetics (diagnostic block) is performed. If pain reduction is adequate the RF procedure will be performed. Problem is that the additive value of this diagnostic block is never proved. It is likely that the diagnostic blocks are superfluous.

Study objective

- 1.) To determine the diagnostic value of a intra-articular injection with local anesthetics in the SIJ followed by RF SIJ denervation.
- 2.) To determine the diagnostic value of a set of 5 SI provocation tests at examination, of which at least 3 are positive, followed by RF SIJ denervation.

Study design

We select patients with CLBP and pain over the SI joint, over the so called Fortin area. Selection takes place on basis of the interview and on the physical examination. After inclusion and informed consent the patients will be scheduled for an intra-articular injection in the SIJ and for a RF SIJ denervation at the operation room of the Gelre hospital Apeldoorn. The treatments are standard procedures for patients with CLBP.

The patients will receive a diagnostic block with a short acting local anesthetic and, on another day, a confirmatory block with a long acting local anesthetic. The amount and duration of pain reduction are registered. Next, a RF SIJ denervation will be performed. The injection and the RF SIJ denervation are performed by different anesthesiologists.

In advance of the diagnostic block the patient is examined by a manual therapist with set of 5 SI provocation tests. All patients are asked to answer some questionnaires (Oswestry, Roland Morris, SF 36) to determine the impact of their pain on their daily activities. After the RF SIJ denervation there is a follow up for 1 year. During the follow up the study data are collected by a research assistant.

After 6 month additive treatments will be started if necessary.

This study will be executed in the outpatient clinic and operating theater of the department of anesthesiology and pain management of the Gelre Ziekenhuizen location Juliana.

Intervention

Injections in the sacro-iliac joint

Radiofrequency denervation of the sacro-iliac joint

Study burden and risks

Compared to the normal procedures, in this study patients have to fill in several questionnaires, the physical examination will be repeated and patients can be treated with a RF SI procedure regardless the results of the diagnostic tests. There is considerable experience with these procedures and the risks are negligible.

Contacts

Public

Gelre Ziekenhuizen

Postbus 9014
7300DS Apeldoorn

Nederland
Scientific
Gelre Ziekenhuizen

Postbus 9014
7300DS Apeldoorn
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

patients with chronic low back pain, with pain over the SI area.

Exclusion criteria

Severe liver- and/or renal function disorders

Zwangerschap

Radicular pain in the leg with paresis

Diseases of the hip (painful coxartrosis; total hip prothesis)

Tumors in pelvis.

obstipation

incontinence

prolaps

hypertonic pelic musculature

Waddell score > 3 uit 5.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	80
Type:	Anticipated

Ethics review

Not approved	
Date:	13-02-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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

CCMO

ID

NL13164.041.06