Diagnostic blockade of sacroiliac joint in patients with pseudoradicular low back pain.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19885

Source
NTR

Brief title
SI diagnostic blockade

Health condition

sacroiliac joint pain

Sponsors and support

Primary sponsor: Department of Anesthesiology, VU university medical center
Source(s) of monetary or material Support: Third flow of funds: Pain Knowledge Center cooperation funds

Intervention

Outcome measures

Primary outcome

The effect of the diagnostic blockade is evaluated through a 10 items BOX-score (box 1 represents no pain, box 10 represents the worst imaginable pain). Patients will fill the BOX-

score (diary) in at home 3 times a day, during at least 4 weeks after a blockade.

Secondary outcome

With the Roland Disability questionnaire and Oswestry Low Back Pain Disability Index the limitation caused by low back pain will be assessed. Global health will be assessed using the short form (SF)-36 and COOP-Wonca questionnaire. Additionally the duration of a pain free period and daily pain medication use will be reviewed.

Study description

Background summary

Objective:

To compare the efficacy of diagnostic blockade with lidocaine or lidocaïne with methylprednisolone to placebo in reducing the pain in patients with sacroiliac joint pain. In all patients a single blockade of a sacroiliac joint will be performed. The individual patient will be included at random to one of three trial groups:

1) group which will receive an injection of 10ml lidocaine,

2) group which will receive an injection of 9ml lidocaine with 40 mg mathylprednisolone,

3) 10ml of 0,9% NaCl in a placebo group. All the injections will be performed under a fluoroscopic guidance. The good position of the injection needle in the sacroiliac joint will be confirmed with contrast material. Afterwards three x-ray photos of the sacroiliac joint in three dimensions will be taken. Outcome will be assessed during 4 weeks after the intervention with BOX-score as a primary outcome. Secondary outcomes concern to Roland Disability questionnaire, Oswestry Low Back Pain Disability Index, COOP-Wonca questionnaire and SF-36, the duration of a pain free period and additionally a daily pain medication use. The outcome will be compared with a baseline, one week prior an injection. The follow up will be carried out for maximum 3 month after the injection.

Study objective

1. In patients with non-specific low back pain, 10 ml lidocaine 2% reduce the pain more then 2 cm at the BOX-score compare to the placebo group;

2. In patients with non-specific low back pain, 9 ml lidocaine 2% with 1 ml corticosteroid (40 mg methylprednisolone) reduce pain more then 2 cm at the BOX-score compare to the placebo group;

3. In patients with non-specific low back pain, 9 ml lidocaine 2% with 1 ml corticosteroid (40

mg methylprednisolone) reduce pain more then 2 cm at the BOX-score compare to the lidocaine group.

Study design

N/A

Intervention

Patients will undergo diagnostic blockade of sacroiliac joint. Due to randomization individual will get lidocaine, lidocaine with corticosteroide or placebo.

Contacts

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Eligibility criteria

Inclusion criteria

1. Pseudoradicular character of pain;

2. Pain below L5;

3. Pain localized above sulcus sacralis;

4. Unilateral pain;

5. Age 18- 70;

6. Three or more positive provocation tests for sacroiliac joint pain;

7. Patient has to speak Dutch;

8. Informed consent is required.

Exclusion criteria

1. Allergy to iodine, lidocaine or cortocosteroide;

2. Pregnancy;

3. General contraindications for invasive treatment;

4. Appearance of a specific cause of low back pain (red flags);

5. Participation in another study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2005
Enrollment:	63
Type:	Actual

Ethics review

Positive opinion

Date:	21-09-2005
Application type:	First submission

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
NTR-new	NL395
NTR-old	NTR435
Other	: N/A
ISRCTN	ISRCTN91421011

Study results

Summary results
N/A