

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

Submission date 27/01/2006	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 27/01/2006	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 06/07/2009	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

NTR435

Study information

Scientific Title

Acronym

SI diagnostic blockade

Study objectives

1. In patients with non-specific low back pain, 10 ml lidocaine 2% reduces the pain more than 2 cm at the BOX-score compared to the placebo group
2. In patients with non-specific low back pain, 9 ml lidocaine 2% with 1 ml corticosteroid (40 mg methylprednisolone) reduces pain more than 2 cm at the BOX-score compared to the placebo group
3. In patients with non-specific low back pain, 9 ml lidocaine 2% with 1 ml corticosteroid (40 mg methylprednisolone) reduces pain more than 2 cm at the BOX-score compared to the lidocaine group

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Randomised, double blind, placebo controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Sacroiliac joint pain

Interventions

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

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

lidocaine, methylprednisolone

Primary outcome(s)

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, for at least 4 weeks after a blockade.

Key secondary outcome(s))

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.

Completion date

01/09/2007

Eligibility

Key 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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

Not Specified

Key exclusion criteria

1. Allergy to iodine, lidocaine or corticosteroid
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

Date of first enrolment

01/09/2005

Date of final enrolment

01/09/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

VU University Medical Center

Amsterdam

Netherlands

1007 MB

Sponsor information

Organisation

VU University Medical Center, Department of Anesthesiology (Netherlands)

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Pain Knowledge Center (cooperation funds) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration