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

Submission date	Recruitment status	[ ] Prospectively registered
27/01/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/01/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/07/2009	Musculoskeletal Diseases	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/09/2005

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Not Specified

Target number of participants

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)

Sponsor details
P.O. Box 7057
Amsterdam
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1007 MB

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Pain Knowledge Center (cooperation funds) (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