A Randomised controlled Trial on the Effect of local analgesia for pain relief after Minimal Invasive Sacro-Iliac joint fusion

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To determine whether SI infiltration with 1.5-5cc bupivacaine 0.25% is superior to placebo (intraarticular injection of 1.5-5cc NaCl 0.9%) in reducing wound pain in patients after MISJF, and to determine whether opioid use in the 2 days after...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON51208

Source
ToetsingOnline

Brief title
ARTEMIS

Condition

- Joint disorders

Synonym
Pelvic instability, Sacroiliac joint dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum

Source(s) of monetary or material Support: Zuyderland

Intervention

Keyword: Analgesia, Pain, Sacroiliac joint dysfunction, Sacroiliac joint fusion

Outcome measures

Primary outcome

Primary endpoints: group difference in NRS pain score during the first 48h after surgery between intervention and placebo, with interval measurements at recovery entry, recovery exit, 2, 4, 6 and 24 hours.

Secondary endpoints: Total postoperative opioid consumption at 48 hours postoperatively with interim measurements at 2, 4, 6 and 24 hours. Patient satisfaction (measured by EQ-5D and GSRI), hospital stay in days and number of adverse events.

Secondary outcome

1. To determine whether SI joint infiltration with bupivacaine 0.25% leads to a reduction in cumulative opioid use until 48 hours postoperatively with measurements at 2, 4, 6, 24 and 48 hours compared to placebo.

2. To determine whether SI joint infiltration with bupivacaine 0.25% leads to higher patient satisfaction than placebo.

3. To determine whether SI joint infiltration with bupivacaine 0.25% leads to shorter hospital stay than placebo.

4. To determine whether SI joint infiltration with bupivacaine 0.25% leads to

less adverse events than placebo.

Study description

Background summary

Minimally invasive sacroiliac joint fusion (MISJF) is a surgical procedure to treat chronic low back pain due to sacroiliac (SI) dysfunction. During the minimally invasive procedure, the SI joint is stabilized by implants inserted percutaneously under fluoroscopy guidance. Postoperatively, patients often report a lot of pain, which contributes to patients taking high doses of painkillers (opioids e.g.) and preventing early mobilization.

Study objective

To determine whether SI infiltration with 1.5-5cc bupivacaine 0.25% is superior to placebo (intraarticular injection of 1.5-5cc NaCl 0.9%) in reducing wound pain in patients after MISJF, and to determine whether opioid use in the 2 days after surgery is significantly higher in the placebo group.

Study design

Double Blinded Randomized Controlled Trial (blinding for the patient, clinician, researcher and statistician).

Intervention

Intra-articular injection with 1.5-5 cc bupivacaine 0.25% or placebo (1.5-5 cc NaCl 0.9%)

Study burden and risks

Infiltration of the SI joint is currently standard care for orthopedic surgeons and anesthesiologists worldwide. It is done to diagnose and treat SI dysfunction. Intraoperatively infiltrating the SI joint has been performed by several spine surgeons, including the team in Zuyderland MC. Minimally invasive sacroiliac joint fusion is generally perceived as a painful procedure. Pain prevents patients to mobilize properly after surgery, which increases complication risk. Postoperative pain is classically treated using opioids, which themselves have side effects and impact on the length of hospital stay. The burden for patients participating in this randomized trial is low. Patients are asked to fill out a questionnaire (EuroQol - 5D and General Surgery Recovery Index) concerning Patient Related Outcome Measurements

(PROMS). As part of the study, NRS pain scores are additionally taken at 2, 4, 6, 24 and 48 hours after surgery. There are no extra visits to the outpatient clinic. There are no benefits in participating in this study compared to care as usual.

Contacts

Public
Zuyderland Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419 PC
NL
Scientific
Zuyderland Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419 PC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Indication for MISJF surgery.
2. Age over and equal to 18 years.
3. Informed consent prior to this study.

Exclusion criteria

1. Revision surgery.
2. Intraoperative inability to infiltrate the SI joint.
3. Contra-indications for the use of bupivacaine or other amide type local anesthetics, anesthesia or surgery.
4. Inadequate command of the Dutch language.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2021
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO Date:	04-06-2021
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	29-11-2021
Application type:	Amendment

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

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
CCMO	NL76457.096.21
Other	NL9151