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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28172

Source
NTR

Brief title
ARTEMIS

Health condition

Sacroiliac joint dysfunction

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

The primary outcome is the group difference in VAS between intervention and placebo during

the first 48h after surgery. With interval measurements at recovery entry, recovery exit, 2, 4, 6, 24 and 48 hours.

Secondary outcome

The group difference in cumulative opioid use at recovery, 2, 4, 6, 24 and 48h after surgery.

Patient satisfaction measured using General Surgery Recovery Index (GSRI) and Visual Analogue Scale (VAS) satisfaction. Patients will fill out the questionnaire 24 hours after surgery. In addition, VAS leg pain and back pain will be filled out 24 hours after surgery.

Adverse events; postoperative infection, deep venous thrombosis, hematoma, neurological deficits and other complications as pneumonia, urine retention or urinary tract infection. Adverse events will be followed up to 30 days.

Hospital stay defined as days spent in hospital after surgery.

Study description

Background summary

Rationale: 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.

Objective: To determine whether SI infiltration with 1.5-5cc bupivacaine 0.25% is superior to placebo (intraoperative epidural 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).

Study population: A total of 42 patients over 18 years old undergoing MISJF.

Intervention: Intraoperative intraarticular injection in SI joint under fluoroscopy guidance with application of analgesic (bupivacaine 0.25%) or placebo (NaCl 0.9%).

Main study parameters/endpoints: Primary endpoints: group difference in VAS 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 using

General Surgery Recovery Index (GSRI) and Visual Analogue Scale (VAS) satisfaction. Patients will fill out the questionnaire 24 hours after surgery. In addition, VAS leg pain and back pain will be filled out 24 hours after surgery, hospital stay in days and number of adverse events.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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, VAS 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.

Study objective

Sacroiliac joint infiltration with bupivacaine 0.25% is superior to placebo in reducing post-operative pain.

Study design

entry and exit recovery, 2, 4, 6, 24 and 48 hours postoperatively

Intervention

Minimally invasive sacroiliac joint fusion will be performed as standard care. The patient is placed in prone position. Intraoperative fluorscopy is used during surgery for optimal placement of implants. After anesthesia is administered the patient is prepped in sterile fashion. Pelvic inlet and outlet views are utilized to obtain an appropriate starting point. A 3cm lateral incision is made across the sacral midline. A guide pin is placed across the ilium and across the SIJ. A drill is used to create a pathway and decorticate the bone. A triangular broach is then used to further decorticate the bone and prepare the pathway to receive the first implant. This implant is mostly seated within the sacral ala. The second implant is generally located above or adjacent to the S1 foramen and the third between the S1 and S2 foramen. The incision is then irrigated with bupivacaine and the tissue layers are sequentially closed.
After closure of the incision a spinal needle is used to infiltrate the SI joint (intraarticular) under fluoroscopy guidance. Either bupivacaine 0.25% 1.5-5cc (intervention) or NaCl 0.9% 1.5-5cc (placebo) will be infiltrated. After surgery patients will be transported to the recovery room, where they will be monitored for a minimum time of one hour.

Contacts

Public
Zuyderland Medical Center
Sem Hermans

+31627453199
Scientific
Zuyderland Medical Center
Sem Hermans

+31627453199

Eligibility criteria

Inclusion criteria

1. Indication for MISJF surgery.
2. Age over 18 years.
3. Psychosocially, mentally, and physically able to fully comply with this study protocol.
4. Informed consent prior to this study.

Exclusion criteria

1. Revision surgery.
2. Contra-indications for the use of bupivacaine or other amide type local anesthetics, anesthesia or surgery.
3. 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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	31-01-2021
Enrollment:	42
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL9151
Other	METC Z : Z2020271

Study results