Can Ropivacaïn 1% replace morphine intrathecal in total hip replacement

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Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON31034

Source
ToetsingOnline

Brief title
Ropivacain as replacement for morphine intrathecal

Condition

- Other condition
- Joint disorders

Synonym
arthrosis

Health condition

totale heup operatie

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: niet

Intervention

Keyword: morphine intrathecal, postoperative pain, ropivacaïn, Total hip replacement

Outcome measures

Primary outcome

Pain scores (VAS)

Itching

Nausea and/ or vomiting

Patint satisfaction

Secondary outcome

none

Study description

Background summary

In recent past we had a few patients (4) who were allergic to morphine. That is why we gave them a femoral block with ropivacaïne 1% 30mL after a total hip repair. Later information learned that it was a succesful treatment with very good results on postoperative pain. Besides that, it was reported that there were less side effects such as itching, nausea and vomiting. Patients were very satisfied. For this we would like to investigate whether the method of postoperative pain treatment could be changed. In this investigation we compare two groups of 10 patients. One group receive anesthesia as usual in our hospital naamely spinal anesthesia with 17,5 mg bupivacaïn with morphine 100 micrograms intrathecal. The other group will receive spinal anesthesia 17,5 mg bupivacaine and a femoral block with 300 mg ropivacaïne,

Study objective

Objective is to compare the two groups whether the pain scores are at least the

same. Also will be noticed if the incidence of side effects of morphine intrathecal are less (e.g. itching, nausea and/ or vomiting and urine retention, although this is not an iten because the patients get a urine catheter) Patients satisfaction will also be noted. If the results are positive for the femoral block we will change our practice.

Study design

Two groups patients seen on the preoperative poli will be asked to participate in this investigation. The assignment of treatment will be made in the holding. The patient will not know in which group he or she is assigned. (single blinded) Comparisons will be made of the mean VAS of the same time (t-test)The incidence of itching, nausea and/ or vomiting will be noted. Also the first moment of patients request to extra pain killers is noted. We think that 10 patients per group is enough, because we are interested in clinically important differences. If larger numbers ar needed it is more a academic difference.

Study burden and risks

None besides the operation itself.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Need to be operated for a total hip repair

Exclusion criteria

Known allergies for ropivacaïne or morphin

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Not approved	
Date:	31-12-2008
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL19593.101.07