

# Title (English)

**\*Optimization of a postoperative multi modal paincare protocol after total knee replacement: comparison of the femoral nerve block with the intra-articular infiltration technique, a prospective randomized double blinded controlled trial.\***

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Assessment of the additional effect of a peripheral pain management technique to regular PCA controlled intravenous morphine technique. Also the two peripheral pain management techniques will be compared: femoral nerve block technique and the intra-...

|                              |                 |
|------------------------------|-----------------|
| <b>Ethical review</b>        | Approved WMO    |
| <b>Status</b>                | Recruiting      |
| <b>Health condition type</b> | Joint disorders |
| <b>Study type</b>            | Interventional  |

## Summary

### ID

NL-OMON32363

### Source

ToetsingOnline

### Brief title

P(postoperative peripheral pain protocol)-4 study

### Condition

- Joint disorders

**Synonym**

gonarthrosis, osteoarthritis of the knee

**Research involving**

Human

**Sponsors and support**

**Primary sponsor:** Isala Klinieken

**Source(s) of monetary or material Support:** aanvraag bij anna fonds ingediend

**Intervention**

**Keyword:** Femoral block, Intraarticular infiltration, Postoperative Pain Management, Total knee replacement

**Outcome measures****Primary outcome**

VAS-pain and morphine useage after 24 hours postoperatively

**Secondary outcome**

Mobility variables (range of motion of the replaced knee joint, 3-metre walking

test), morphine related side-effects (gastro-intestinal (nausea, vomitis,

obstipation), neurological (alertness), miction, itching. Clinical scores:

WOMAC, Knee society score, SF-36, satisfaction.

**Study description****Background summary**

Until now, intravenous morphine is still mainstay in pain management after knee total arthroplasty. Given the systemic character of this technique and the well-known morphine side-effects, the pain reduction and rehabilitation are still not yet optimal. Developments in peripheral (additive) pain treatment techniques take a flight. The nervus femoralis block technique with a local anaesthetic has the advantage of loco-regional pain management. The intra-articular infiltration technique with a local anaesthetic blocks the pain at its source: tissue damage caused by the operative intervention. Better pain

management, swifter mobilisation and less morphine associated side-effects as a result.

## **Study objective**

Assessment of the additional effect of a peripheral pain management technique to regular PCA controlled intravenous morphine technique. Also the two peripheral pain management techniques will be compared: femoral nerve block technique and the intra-articular infiltration technique with a known local anaesthetic.

## **Study design**

In a randomised double blind placebo controlled trial set-up patients with arthritis of the knee undergo a total knee operation. These patients will receive postoperative basic pain treatment by means of intravenous morphine (2,0mg/ml) according to the PCA (patient controlled analgesia) principle. All patients will receive a femoral nerve catheter (in the groin) and a intraarticular catheter (in the knee). The groups will be created: group 1 (continuous local anaesthetic via a groin catheter and placebo via the intraarticular catheter), group 2 (continuous placebo via a groin catheter - and local anaesthetic via intraarticular catheter) and group 3 (control group) (continuous placebo via a groin catheter - and via intraartculaire catheter). levobupivacaine 0.25% will be used as local anaesthetic and saline in the same volume quantities will be used as placebo 24 hours postoperative. VAS for pain, degree of mobility and (morphine related) side effects are scored postoperatively.

## **Intervention**

peripheral pain treatment technique with a known local anaesthetic by means of the femoral nerve block technique or the intraarticular infiltration technique of the knee by means of local infusion with catheters after total knee replacement procedures.

## **Study burden and risks**

Low. Femoral catheters are introduced before spinal anaesthesia is given, thereby insuring effectiveness and securing optimal placement. The patient can experience some inconvenience of this. The intraarticular catheter will be left behind during closure of the wound. Both catheters will be removed 24-hours postoperatively along with the wound drain before starting exercising.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Symptomatic osteoarthritis of the knee,

### Exclusion criteria

Other orthopaedic comorbidity inhibiting normal rehabilitation, contra's concerning spinal anaesthesia, inability performing in a group, > 85 years

## 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:       | Recruiting |
| Start date (anticipated): | 12-10-2008 |
| Enrollment:               | 150        |
| Type:                     | Actual     |

## Ethics review

|                    |                               |
|--------------------|-------------------------------|
| Approved WMO       |                               |
| Date:              | 22-05-2008                    |
| Application type:  | First submission              |
| Review commission: | METC Isala Klinieken (Zwolle) |

## 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

CCMO

### ID

NL22448.075.08