# What is the most optimal treatment strategy for an adolescent with knee complaints?

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What is the most optimal treatment strategy for children / adolescents with knee complaints? Our hypothesis is (based on the invasive surgical procedure) patients that will be surgical treated (index group) have a clinical relevant gain of pain...

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|---|---|
| **Ethical review** | Not approved |
| **Status** | Will not start |
| **Health condition type** | Bone disorders (excl congenital and fractures) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON43912

**Source**
ToetsingOnline

**Brief title**
Treatment strategy for adolescent with knee complaints

### Condition

- Bone disorders (excl congenital and fractures)

**Synonym**
non-traumatic knee complaints; chronic knee pain

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Maxima Medisch Centrum
**Source(s) of monetary or material Support:** maatschap Orthopedie

## Intervention

**Keyword:** adolescent, knee complaints, treatment strategy

## Outcome measures

### Primary outcome

NRS (numeric rating scale) for pain after one year of follow-up

### Secondary outcome

amount of pain at the follow-up moments; function score knee; medication use;

adverse events; satisfaction score patient.

# Study description

### Background summary

Treatment of adolescents with non-traumatic knee complaints is a challenge for an orthopedic surgeon. The initial treatment choice will be non-operatively. For the non-responders of this traject, an operative treatment is an option. Which patients will respond to the non-operative traject or not, and what the most effective treatment is for the the so called non-responders is till date not clear.

### Study objective

What is the most optimal treatment strategy for children / adolescents with knee complaints? Our hypothesis is (based on the invasive surgical procedure) patients that will be surgical treated (index group) have a clinical relevant gain of pain relief after one year compared to the control group (effect size of minimally 0.5).

### Study design

prospective follow-up study with a nested open-label randomized clinical study

### Intervention

a) *index treatment* surgical intervention, a deroterening osteotomy of the femur

b) *control treatment*: painteam; focused on pain medication and TENS.

### Study burden and risks

The surgical intervention is one of the treatment options for this target population in Máxima Medical Center. Patients which will not respond after 1 year of follow-up on the painteam treatment; will have the oppurtunity to undergo the surgical treatment. The additional burden is that we ask time of the patient to fill in two questionnaires.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)

### Inclusion criteria

age between 12-17 year; pain in upper leg region, knee and / or lower leg; non-traumatic related complaints; *kneeing in* fenomen; increased internal rotation hip, asymmetric external rotation hip; increased anteversion femur assessed on CT scan; normal mechanical axis; normal MRI.

### Exclusion criteria

insufficient command of Dutch language (to fill in questionnaires); not willing to particpate; contra-indications for surgical intervention.

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 200 |
| Type: | Anticipated |

## Ethics review

Not approved

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|---|---|
| Date: | 08-06-2016 |
| Application type: | First submission |
| Review commission: | METC Maxima Medisch Centrum (Veldhoven) |

# 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 | NL54673.015.15 |