# A Randomized Controlled Trial of AttraX® Putty vs. conventional open-wedge osteotomy without gap filler in open-wedge osteotomy

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON53187

**Source**
ToetsingOnline

**Brief title**
AXOS

### Condition

- Other condition
- Joint disorders

**Synonym**
arthrosis, Unicompartimental osteoarthritis

**Health condition**

Standsafwijking

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** Nuvasive

## Intervention

**Keyword:** Gap filler, Osteotomy, Postoperative pain, Randomized controlled trial

## Outcome measures

### Primary outcome

The main study endpoint is the mean NRS pain during the first week

postoperative.

### Secondary outcome

The secondary study endpoints are faster accelerated rehabilitation/regaining

function, reduction of local blood loss, accelerated, bone union, and

comparable surgical feasibility

# Study description

### Background summary

Realignment osteotomies around the knee are a proven surgical treatment for unicompartmental knee osteoarthritis and a malalignment. Osteotomies can be very painful in the early postoperative phase. This is probably due to a combination of bony cut (bone pain) and postoperative hematoma (bleeding and leakage of the bone marrow) in the surrounding soft tissue. The AttraX® Putty can be used as a gap filler in open wedge osteotomies to potentially reduce postoperative pain by reducing the bleeding from the bone gap.

### Study objective

The main aim of this study is to determine whether early postoperative pain is decreased when the osteotomy gap is filled with AttraX® Putty, compared to

conventional open wedge osteotomy without filling the gap. The secondary aims are faster accelerated rehabilitation/regaining function, reduction of local blood loss, accelerated bone union, and comparable surgical feasibility.

### Study design

Single-blinded, prospective, randomized controlled trial.

### Intervention

According to a randomization scheme, the osteotomy gap will be filled with either the synthetic ceramic material AttraX® Putty or without a gap filler (conventional method).

### Study burden and risks

Patients may have the advantage of experiencing less pain postoperatively if they are treated with the AttraX® Putty, which can contribute to a faster rehabilitation. Risks to the AttraX® Putty group may include an allergic reaction, failure to promote bone fusion and excessive bone growth. However, the preclinical studies and clinical studies show that the use of AttraX® Putty is safe for use in humans.

## 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

1. Patients above 18 years with an indication for an open-wedge osteotomy of the femur, tibia or double level due to unicompartimental OA.
2. Comply with all aspects of the treatment, including CT scans, Xrays and 1-year follow-up
3. Informed consent

### Exclusion criteria

1. Osteotomy for indication of cartilage treatment or other knee surgeries than unicompartimental OA
2. Correction using an open wedge above 10 mm
3. Pregnant women at the time of enrolment or women who are planning to become pregnant during the duration of the study
4. Inability to communicate in Dutch or English

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 20-09-2023 |
| Enrollment: | 40 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | Attrax Putty |
| Registration: | Yes - CE intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 19-07-2023 |
| Application type: | First submission |
| Review commission: | METC NedMec |

## 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 |
|---|---|
| Other | clinicaltrials.gov |
| CCMO | NL84534.041.23 |