

# Joint distraction in the treatment of knee osteoarthritis: efficacy and underlying mechanisms

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<b>Registration date</b> 26/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/08/2021	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

Joint distraction in the treatment of knee osteoarthritis: efficacy and underlying mechanisms

### Study objectives

Joint distraction is a relatively new approach in the treatment of severe Osteoarthritis (OA). Clinical efficacy has been proven for hip and ankle OA.

### Hypothesis:

A two month distraction period results in similar clinical beneficial effects as a three month distraction period.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approval received from the Medical Ethical Committee of the University Medical Centre Utrecht on the 28th July 2004.

### Study design

Non-randomised, non-controlled, interventional clinical trial

### Primary study design

Interventional

### Secondary study design

Single-centre

### Study setting(s)

Other

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Osteoarthritis

### Interventions

Joint distraction applies temporary (two months) relief of mechanical wear and tear of the articular cartilage surfaces forming a joint. Nutrition of the cartilage is maintained due to intra-articular fluid pressure changes during treatment. Additionally subchondral sclerosis is diminished, diminishing mechanical stresses on the cartilage after treatment.

### Intervention Type

Other

**Phase**

Not Specified

**Primary outcome measure**

Pain (according to the The Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC])

**Secondary outcome measures**

Functional disability (according to the WOMAC)

**Overall study start date**

28/07/2004

**Completion date**

01/03/2010

## Eligibility

**Key inclusion criteria**

1. Age less than 55 years
2. Osteoarthritis, primary in the tibio-femoral joint, uni or bilateral
3. Severe osteoarthritis considered for joint replacement surgery/osteotomy

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

3

**Key exclusion criteria**

1. Osteoarthritis in both knees
2. Primary retro-patellar osteoarthritis
3. Deviation of the mechanical axis greater than 10 ° (independent of cartilage damage)
4. Primary intra-articular inflammation
5. Psychological problems, not allowing two months distraction

**Date of first enrolment**

28/07/2004

**Date of final enrolment**

01/03/2010

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

University Medical Centre Utrecht (UMCU)

Utrecht

Netherlands

3508 GA

## **Sponsor information**

**Organisation**

University Medical Centre Utrecht (UMCU) (The Netherlands)

**Sponsor details**

Department of Rheumatology and Clinical Immunology

P.O. Box 85500

Utrecht

Netherlands

3508 GA

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.umcutrecht.nl/zorg/>

**ROR**

<https://ror.org/04pp8hn57>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Dutch Arthritis Association (Reumafonds) (The Netherlands)

## **Results and Publications**

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		12/05/2011	20/08/2021	Yes	No