

# Inlay versus brace treatment for medial knee osteoarthritis: a randomised trial

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/03/2015	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
NTR484; 3

# Study information

## Scientific Title

Inlay versus brace treatment for medial knee osteoarthritis: a randomised trial

## Acronym

SOLE

## Study objectives

An inlay for the treatment of medial knee osteoarthritis will result in pain reduction, function improvement and better compliance then brace treatment.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Received from local medical ethics committee

## Study design

Randomised open-label active-controlled parallel-group trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

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

Arthritis, Osteoarthritis

## Interventions

Group 1: lateral wedge sole (inlay)

Group 2: valgisation knee brace (brace)

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome measure

Will inlay treatment for patients with symptomatic medial knee osteoarthritis yield better results than brace treatment?

Measurements:

1. Painscore (VAS)
2. Hospital for Special Surgery (HHS) Knee Service Rating System
3. Western Ontario and McMaster University Osteoarthritis Index (WOMAC)

### **Secondary outcome measures**

1. Will there be a functional difference between both groups?

Measurements:

- 1.1. Gait analysis (knee adduction moment, toeing-out, knee extension moment)
- 1.2. Knee range of motion
- 1.3. Patient satisfaction
- 1.4. Maximum walking distance

2. Will conservative treatment (inlay or brace) give a favourable outcome for medial knee osteoarthritis?

Measurements:

- 2.1. Dual energy x-ray absorptiometry (DEXA-scan)
- 2.2. Osteoarthritis markers (serum and urine)
- 2.3. Hip-knee-ankle (HKA) angle

### **Overall study start date**

01/10/2005

### **Completion date**

31/12/2007

## **Eligibility**

### **Key inclusion criteria**

Patients (male and female) with symptomatic medial osteoarthritis of the knee. Patients will be included after informed consent given and baseline measurements made.

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

100

### **Key exclusion criteria**

1. Below 35 or above 60 years of age
2. Symptoms not related to medial osteoarthritis of the knee
3. Not able to speak or understand Dutch.

**Date of first enrolment**

01/10/2005

**Date of final enrolment**

31/12/2007

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

Erasmus University Medical Centre

Rotterdam

Netherlands

3000 CB

## Sponsor information

**Organisation**

Erasmus Medical Centre (Netherlands)

**Sponsor details**

Dr. Molewaterplein 40/50

Rotterdam

Netherlands

3000 CA

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/018906e22>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Erasmus Medisch Centrum

**Alternative Name(s)**

Erasmus Medical Center, Erasmus MC, Erasmus Universitair Medisch Centrum, Erasmus University Medical Center, Universitair Medisch Centrum Rotterdam, Erasmus Universitair Medisch Centrum Rotterdam, EMC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Netherlands

**Funder Name**

Algesiologie Foundation (Stichting Algesiologie) (Netherlands)

**Funder Name**

The Anna Fonds Foundations (Stichting Anna Fonds) (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>	results	01/07/2010		Yes	No