

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

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| Submission date 27/01/2006 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 27/01/2006 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 12/03/2015 | Condition category 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

Will inlay treatment for patients with symptomatic medial knee osteoarthritis yield better results then 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)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/07/2010 | | Yes | No |