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

Submission date	Recruitment status	[ ] Prospectively registered
27/01/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/03/2015	Musculoskeletal Diseases	

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

Primary study design
Interventional

Study design
Randomised open-label active-controlled parallel-group trial

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
Algesiology 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