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

Submission date	Recruitment status	[ ] Prospectively registered
26/02/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/08/2021	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

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

Study type(s)
Treatment

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

Key secondary outcome(s))
Functional disability (according to the WOMAC)

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

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)

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Charity

Funder Name
Dutch Arthritis Association (Reumafonds) (The 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		12/05/2011	20/08/2021	Yes	No