Grip on knee Osteoarthritis; DIstraction Versus Arthroplasty (GODIVA) for young knee osteoarthritis patients in regular care.

Published: 10-12-2021
Last updated: 05-06-2025

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Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Joint disorders
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON54110

Source
ToetsingOnline

Brief title
GODIVA

Condition

- Joint disorders

Synonym
arthrosis osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Collectebussenfonds,Vakministerie

Intervention

- Surigical procedure

Keyword: knee arthroplasty, knee joint distraction, osteoarthritis

Explanation

N.a.

Outcome measures

Primary outcome

Primary endpoint: Western Ontario and McMaster Universities Arthritis Index
 (WOMAC) total score.
For the substudy: MRI, CT, DEXA image markers and blood and urine biochemical
 markers

Secondary outcome

Main secondary outcomes: WOMAC/KOOS Pain, stiffness, and physical function
 sub-scores, quality of life (EQ-5D, SF-36), radiographic joint space width (KJD
 only); adverse events, and productivity and healthcare cost. All assessed over
 24 months.

Study description

Background summary

For relatively young (<= 65 year) patients with severe knee osteoarthritis (OA) with persistent pain, insufficiently responding to conservative therapy and joint preserving surgery (*end-stage knee OA*) a knee prosthesis (KP) is currently the most commonly used treatment. When a first prosthesis is placed at a young age, patients often need revision surgery later in life. Revision surgery is complex, costly, and accompanied by multiple complications. The increasing life expectancy, focus on patient empowerment, and the wish to stay active and independent up to high age, will probably further increase the number of revision surgeries. As such, preventing revisions surgery is key. When a first prosthesis is placed after the age of 65, data show that the need for revision surgery becomes significantly lower.
Knee joint distraction (KJD) is a joint preserving treatment that significantly

postpones the need for a primary knee prosthesis (up to ~ 10 years in 50% of cases). KJD is proven to be effective in reducing pain and stiffness and improving function, although effects seem slightly less compared to a knee prosthesis. As assessed by *Zorg Instituut Nederland*, KJD is promising but the current evidence still too limited and thus not yet suitable for reimbursement. Even in case KJD is less effective, if this is clinically acceptable (non-inferior), the reduced chance for burdensome revision surgery might still make it a treatment of choice.

Study objective

To determine whether KJD is non-inferior on patient reported effectiveness as compared to a KP (i.e. usual care) for relatively young patients with end-stage knee OA.
For the substudy: the primary objective is to predict the benefit from knee distraction treatment by peri-articular bone characteristics.

Study design

Pragmatic, open, randomized, multi-centre, non-inferiority trial with 24 months follow-up.
For the substudy: observational study as add-on study

Intervention

KP is indicated and surgically implanted according to regular clinical practice (can be a total- or unicompartmental KP, in line with local practice in consultation with the patient and conform local national guideline by Dutch orthopaedic society (NOV)). KJD treatment is performed according to the current approved concept NOV recommendations for practice.

Study burden and risks

The benefit of a KP over KJD might be the swifter and slightly better clinical effect of treatment although at the expense of the original joint and with the higher risk of revision surgery later in life. The benefit of the KJD over a KP is that the original joint is preserved with the chance of postponing placement of a KP and prevention of revision surgery later in life, although with the burden of a 6-week distraction period with the chance of skin pin-tract infections, and possibly a slightly (non-clinically relevant) lesser clinical benefit.
In both arms, at 7 moments questionnaires have to be filled out and at baseline, and in case of KJD treatment at 24 months a clinic visit takes place in addition to the typically 4 clinic visits performed in regular practice. In both arms a comparable number of knee radiographs is made in regular care and for KJD 1 study specific x-ray will be made at 2 years post-treatment.

In both arms the chance of failure is <5% in the first year after treatment because of multiple reasons, mostly persisting pain, leading to either revision surgery in case of a KP or placement of a first KP in case of KJD. Additionally, there is a chance of infection in both arms. In case of KJD these are primarily superficial skin pin tract infections, in generally successfully treatable with oral antibiotics. In both arms a small chance for deeper infections up to osteomyelitis are seen, needing i.v. antibiotics and/or nettoyage or even removal of the frame in case of KJD or early revision surgery in case of KP. Rehabilitation after the intervention(period) is similar for both treatment arms.

For the substudy: the burden will be a knee-MRI, knee-CT, and DEXA scan at pre-treatment and 2 years post-treatment, which will take two times an 60-120 min extra out-patient visit time. These image techniques are considered minimally invasive with CT and DEXA with radiation exposure. Additionally, a vena puncture for 2* 7 cc blood samples (serum and plasma) at both timepoints provides a minimal risk. The urine samples are considered riskless.

Contacts

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Trial sites

Trial sites in the Netherlands

Dijklander Ziekenhuis
Target size: 60

OLVG

Target size: 60

FlexClinics
Target size: 30

Ziekenhuisvoorzieningen Gelderse Vallei
Target size: 60

Reinier Haga Orthopedisch Centrum
Target size: 100

Medisch Spectrum Twente
Target size: 60

ZorgSaam
Target size: 60

Sint Jansdal ziekenhuis
Target size: 130

Universitair Medisch Centrum Utrecht
Target size: 50

Maastricht Universitair Medisch Centrum +
Target size: 75

Martini Ziekenhuis
Target size: 50

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Clinical diagnosis of knee OA
- Age <= 65 years and >= 18 years
- Persistent, refractory pain, insufficiently responding to conservative and previous non-surgical therapy
- Structural OA joint damage, indicated by a K&L grade of at least 2
- Able to wear an external fixator and care for it for 6 weeks
- Accepting that the maximal effect of KJD is not present directly after removal of the frame but may take months after frame removal
- Sufficient joint stability (according to the orthopedic surgeon's judgement)
- Flexion (>100 degrees) and extension range (<10 degrees)

- Weight and BMI <120 kg and <35 kg/m2 respectively

Exclusion criteria

- Primary patella-femoral knee osteoarthritis
- Surgical intervention in last 6 months
- Leg-axis deviation > 10 degrees
- Serious osteopenia making placing bone-pins and wearing a frame into a risk (according to the orthopedic surgeon's judgement)
- Coagulation problems making occurrence of thrombosis or embolies into a risk (according to the orthopedic surgeon's judgement)
- Existing endoprosthesis at hip or ankle of the ipsilateral side to prevent infection of existing prosthesis. Whether an endoprosthesis at any other joint is a reason to exclude the patient is according to the orthopedic surgeon's judgment.
- History or presence of joint infection/inflammation
- Hypersensitivity to antibiotics
- Presence of systemic inflammatory disease, like rheumatoid arthritis

For the GODIVA bone substudy: Inability to undergo a knee-MRI or knee-CT and DEXA according to the local enforced criteria in regular health care.

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Other type of control
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	15-02-2024
Enrollment:	1200

Duration:	24 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO Date:	24-08-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	19-10-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-11-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-12-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-07-2024
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-11-2024
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	28-01-2025
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-04-2025
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-05-2025
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL78932.041.21
Research portal	NL-007488