Novel transcatheter arterial embolization for treatment of knee osteoarthritis: a randomized sham-controlled clinical trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON50381

Source
ToetsingOnline

Brief title
Transcatheter arterial embolization treatment of knee osteoarthritis

Condition

- Joint disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
degeneration of joint cartilage

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Cook Medical

Intervention

Keyword: arterial, embolization, osteoarthritis, transcatheter

Outcome measures

Primary outcome

Change of pain (measured with Knee injury and Osteoarthritis Outcome Score)

between baseline and 4 months follow-up.

Secondary outcome

NA

Study description

Background summary

Osteoarthritis (OA) is the most common joint disease resulting in severe morbidity and, of all joint diseases, incurs the most years lived with disability and highest costs on a population level.
There are no definite or disease-modifying treatment options for OA: current therapies are purely symptomatic, temporary and oftentimes ineffective, or entail major joint replacement surgery in end-stage OA.
Joint replacement, however, has limited durability, carries risks of complications, and can be impossible in case of comorbidities. The most frequently affected joint by OA is the knee. It is critical to identify novel therapies to decrease the significant morbidity of knee OA, while delaying the time to joint replacement for as long as possible, because survival rates of knee prosthesis are higher when performed at older age.

An increasing body of literature suggests that periarticular soft tissues, such as synovium, fat pad, and joint capsule that are affected by inflammatory processes, are likely sources of pain in knee OA.

Since pain is the predominant symptom of OA, there is a need for novel therapies for knee OA that reduce pain by targeting the inflammation of periarticular soft tissues.

Study objective

The main objective is to assess whether transcatheter arterial embolization of

neovessels in patients with symptomatic knee OA results in significant pain reduction after 4 months compared to sham treatment.

We hypothesize that novel transcatheter arterial embolization of neovessels is a feasible, effective, and safe treatment for patients with symptomatic radiographic knee OA, resulting in significant improvement of pain symptoms in a period of 4 months follow-up compared to placebo.

Secondary objectives are:
1) to assess whether reduction of neovessels is related to pain relief,
2) to explore whether decrease of inflammation is a mediating factor between neovessel reduction and pain relief,
3) to assess whether transcatheter arterial embolization reduction of neovessels decreases peripheral and central pain sensitization and
4) to assess whether transcatheter arterial embolization improve the outcome at 1, 4, 8 and 12 months compared to placebo of the: ICOAP, painDETECT, EQ-5D-5L and NRS questionnaires.

Study design

Double-blinded randomized placebo-controlled clinical trial

Intervention

One group (n=29) undergoes transcatheter arterial embolization of neovessels around the knee and the other group (n=29) undergoes placebo- embolization.

Study burden and risks

Participants of this study will undergo a blood test for determining the kidney function, 5 questionnaires (Knee injury and Osteoarthritis Outcome Score, Measure of Intermittent and Constant Osteoarthritis Pain, painDETECT, Numeric rating scale (for pain severity, stiffness, and swollenness in the knee) and the EQ-5D-5L questionnaire) will be filled in at 5 different time points.

Pain pressure threshold testing using an algometer will be performed at the same 5 time points.

MRI of the knee with a contrast agent and a duration of approximately 45 minutes will be performed at baseline, 1 and 4 months follow-up.

These measurements will result in five additional hospital visits. All travel expenses made due to these visits will be reimbursed.

The intervention arm undergoes Digital Subtraction Angiography (DSA) during the

intervention.
Therefore, this study arm is at risk for infections of site access, subcutaneous haemorrhage and dissection of the femoral artery.

The radiation exposure is expected to be around 4 mSv.

Only the intervention group will undergo embolization of neovessels. A potential risk of embolization is non-target embolization.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age * 18 years
- Knee pain for a duration of *6 months

- Knee pain (numeric rating scale *4 - *8) on at least half of the days in the preceding month at
time of inclusion
- There is insufficient response of conservative treatment for at least 6 months
- Radiographic knee osteoarthritis (radiographic Kellgren and Lawrence grade 1-3)

Exclusion criteria

- Contra-indications for MRI (e.g. metallic foreign bodies, etc.)
- Contra-indications for angiography
- Renal insufficiency, checked with blood sample test (GFR < 30 ml/min/1,73 m^2);
- Known allergy to contrast agents;
- Patient has known allergies to barium sulfate, 3-aminopropyltrialkoxysilane, polyphosphazene
- Women who are pregnant or lactating
- Intermittent claudication of affected limb
- Intra articular injections in the ipsilateral knee less than 6 months ago
- On the waiting list for joint replacement surgery
- Amitriptyline usage.
- Insufficient command of the Dutch or English language.
- Legally incompetent adults.
- Had previous surgical treatment for knee osteoarthritis (e.g. high tibial osteotomy), excluding
knee arthroscopy
- Has musculoskeletal co morbidity (e.g. rheumatoid arthritis or gout) potentially blurring the
effect of the treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-06-2019
Enrollment:	58
Type:	Actual

Medical products/devices used

Generic name:	Embozene
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	29-11-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-03-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-12-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-09-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-01-2021
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-03-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL65517.078.18