Treatment of medial knee joint pain with the Trammpolin® meniscus prosthesis.

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

Summary

ID

NL-OMON46495

Source
ToetsingOnline

Brief title
AIR - study

Condition

- Joint disorders

Synonym
meniscus injury, Osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: ATRO Medical B.V.
Source(s) of monetary or material Support: ATRO Medical B.V.

Intervention

Keyword: joint pain, meniscus, osteoarthritis, prosthesis

Outcome measures

Primary outcome

Performance of the Trammpolin® meniscus prosthesis in improving pain as assessed by the KOOS Pain Sub-scale at 24 months post-operative compared to baseline (pre-operative).

Secondary outcome

The following exploratory endpoints will be analyzed from the participant data collected from this study:

* KOOS Pain Sub-scale at 6 weeks, 3 months, 6 months and 12 months post-operative compared to baseline (pre-operative).
* Overall KOOS scale at 6 weeks, 3 months, 6 months, 12 months and 24 months post-operative compared to baseline (pre-operative).
* Lysholm scale at 6 weeks, 3 months, 6 months, 12 months and 24 months post-operative compared to baseline (pre-operative).
* IKDC objective scale at 6 weeks, 3 months, 6 months, 12 months and 24 months post-operative compared to baseline (pre-operative).
* X-ray at 6 weeks, 12 and 24 months to evaluate the height of the joint space compared to baseline (pre-operative).
* MRI scan at 12 and 24 months after surgery to evaluate the amount of extrusion of the Trammpolin® meniscus prosthesis.

Study description

Background summary

Young patients (15-45 years old) that have a knee injury and go through a meniscectomy (partial or total removal of the medial meniscus) gradually develop osteoarthritis (OA) of the knee, a chronic and painful condition where the cartilage covering the end of the bones breaks down, causing pain, stiffness and swelling. It can take 5 to 15 or even 20 years to develop OA symptoms. (Finnish Degenerative Meniscal Lesion Study (FIDELITY)(Sihvonen, Paavola et al. 2013) Also, in patients who did not have knee surgery in the past, the medial meniscus may degenerate and lose its function. These patients develop medial joint space narrowing (narrowing of the space between the ends of the bones in the joint due to cartilage loss) and pain. (Badlani, Borrero et al. 2013)

Most patients endure the remaining pain and reduced daily life activities. They use pain medication, get injections with corticosteroids or hyaluronic acid in the knee joint, are referred to physiotherapists and sometime use braces. Patients will gradually lose their mobility, with their quality of life reduced and the additional medical costs for OA patients increased year after year. For these patients, there are no alternative treatment options (Figure 1). When the joint space narrowing proceeds and when there is a *bone-on-bone* situation, only then the patient is eligible for a total knee prosthesis or arthroplasty (TKA). However, in this age group below 65, a TKA give less favourable results and the lifetime of the TKA is limited (on average it lasts 15 years), due to the more active lifestyle of the patient in this relative young patient population.

As a result, many patients suffer from pain and immobility at a relatively young age and are not eligible yet for a TKA. In the US alone there are 50.000 new patients (35-64 years old) every year with a history of partial or total meniscectomy leading to early onset of OA. (Abrams, Frank et al. 2013). As these patients are not eligible for TKA, they are fully relying on physiotherapy, medications, injections to maintain quality of life resulting in significant medical cost for the time period until they will ultimately undergo a TKA.

Consequently, for these young OA patients with history of partial meniscectomy, a timely intervention that would remove the progressing pain, restore mobility and prevents a long trajectory of physiotherapy and pain medication, would be a desirable alternative. Consequently, Trammpolin® meniscus prosthesis was developed as a viable alternative to conventional TKA.

Study objective

The objective of the clinical investigation is to evaluate the performance and the safety of the Trammpolin® meniscus prosthesis system and to demonstrate that the Trammpolin® meniscus prosthesis system is able to provide pain relief in the medial compartment of the knee due to loss of meniscus function, when this is caused by medial partial meniscectomy.

Study design

This is a prospective, multi-center, open label, single arm clinical investigation.

Intervention

A regular arthroscopic inspection is performed through two or three portals in the skin and capsule on the anterior side of the knee. The lateral portal is used for the arthroscopic camera and the medial portal provides access for the surgical instruments like arthroscopic scissors and aiming device. See CIP section 1.7

Study burden and risks

Trammpolin® meniscus prosthesis is a completely new device for replacement of the damaged or dysfunctional medial meniscus. Nevertheless, it is anatomically shaped with friction characteristics and mechanical stability that closely mimics the native meniscus. Several material scientists, tribology experts, biomechanical engineers, biologists and surgeons have worked on the development of Trammpolin® meniscus prosthesis to optimally tune the design of the prosthesis. The aspects determining the prosthesis functionality (material properties, geometry, fixation and surface characteristics) have been separately studied in vitro and in silico to closely match native meniscus properties and are combined in the full prosthesis design. Based on this data, we expect the following benefits:
1. Trammpolin® meniscus prosthesis match the native meniscus and may provide pain relief and an improved quality of life.
2. Trammpolin® meniscus prosthesis may postpone the first total knee replacement in this younger patient category.

The following potential Adverse Device Effects may arise as a result of implanting the investigational device:
1. Dislocation of the device due to loosening from the fixation screws
2. Pain discomfort, caused by oversizing, under sizing, or wrong placement of the implant.
3. Impairment of Range of Motion (RoM) of the knee joint: caused by oversizing, under sizing, or wrong placement of the implant.
4. Post-operative infection of the joint, which requires consecutive surgery with rinsing of the joint and longtime antibiotics, and possible removal of the

implant. This may cause damage to the joint.
5. Neurovascular damage during the procedure: the drilling of the posterior screw may damage the neurovascular structures posterior in the knee (popliteal nerve, artery and vein).
6. Material sensitivity reactions.

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

1. 1. Has medial compartment joint pain with > 6 months ago a medial partial meniscectomy as confirmed by patient history and MRI
2. Has a KOOS Pain of * 75 (100 being the highest attainable and 0 is no pain)
3. Is between age 30 and 65 years (inclusive) at the time of screening
4. Has neutral alignment ± 5º of the mechanical axis, i.e., the angle formed by a line drawn

from the center of the femoral head to the medial tibial spine and a line drawn from the medial tibial spine to the center of the ankle joint, as confirmed by X-ray
5. Is willing to be implanted with the Trammpolin® meniscus prosthesis.
6. Is able to do the study required follow up visits, questionnaires, X-rays, CT-scans, and MRI*s
7. Is able and willing to understand and sign the study Informed Consent Form
8. Is able to read and understand the national language of the country in which the relevant clinical site is located

Exclusion criteria

1. Has a symptomatic knee because of a tear that could be addressed by a repeat partial meniscectomy
2. Has evidence of a modified Outerbridge Grade IV cartilage loss on the medial tibial plateau or femoral
condyle that potentially could contact a Trammpolin® meniscus prosthesis (e.g., a focal lesion > 0.5 cm correlating to a circular defect of > 8 mm in diameter)
3. Has lateral compartment pain and Grade III or Grade IV modified Outerbridge cartilage score in the lateral
compartment
4. Has a varus or valgus knee deformity of > 5º requiring a tibial or femoral osteotomy
5. Has a varus alignment that is not passively correctable
6. Has a laxity level of more than Grade II (IKDC), primary or secondary to an injury of the anterior cruciate ligament (ACL) and/or posterior cruciate ligament (PCL) and/or lateral collateral ligament (LCL) and/or medial collateral ligament (MCL)
7. Has significant trochlear dysplasia, patellar instability or symptomatic patellar misalignment
8. Has patellar compartment pain and Grade III or Grade IV modified Outerbridge cartilage score in the patellar compartment.
9. Compared to a normal knee, has obvious radiological evidence of medial femoral squaring, anatomical variance in the medial tibial plateau, or irregularly shaped cartilage surface
10. Had an ACL reconstruction performed < 9 months prior to surgery
11. Has a BMI > 32.5 at the time of screening
12. Received any type of prosthetic knee implant made of artificial non-resorbable plastic, metal or ceramic, not including the Trammpolin® meniscus prosthesis
13. Has a knee flexion contracture > 10º
14. Has flexion < 90º
15. Had a previous medial femoral condyle surgery (not including microfracture) or High Tibial Osteotomy (HTO)
16. Has insufficiency fractures or avascular necrosis of the medial compartment
17. Has an active infection or tumor (local or systemic)
18. Has any type of knee joint inflammatory disease including Sjogren*s syndrome
19. Has neuropathic knee osteoarthropathy, also known as Charcot joint
20. Has any medical condition that does not allow possible arthroscopy of the knee
21. Has neurological deficit (sensory, motor, or reflex)

22. Is currently involved in another investigation of the lower extremity
23. Anticipates having another lower extremity surgery during the study period
24. Is contraindicated for corticosteroid injections (i.e., patients with allergy to any of the components or with idiopathic thrombocytopenic purpura)
25. Has received any corticosteroid knee injections * 3 months prior to surgery
26. Has chondrocalcinosis
27. Has proven osteoporosis
28. Is on immunostimulating or immunosuppressing agents
29. Has ipsilateral or contralateral lower limb joint conditions that may affect ambulation or KOOS (e.g. have a leg length discrepancy > 2.5 cm [1 inch], causing a noticeable limp)
30. Is a female who is lactating, expecting, or is intending to become pregnant during the study period
31. Is an active smoker
32. Is mentally incapacitated (incapable of appraising or controlling conduct) or have mental disability (e.g., dementia or Alzheimer*s)
33. Is a prisoner
34. Has a condition or be in a situation that, in the Investigator*s opinion, may confound the study results, or may interfere significantly with the subject*s participation in the study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	13-12-2018
Enrollment:	18
Type:	Actual

Medical products/devices used

Generic name:	Trammpolin®
Registration:	No

Ethics review

Approved WMO Date:	11-07-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-09-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-01-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-02-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL64121.091.17
Other	TBD

Study results

Date completed:	03-06-2021
Results posted:	17-12-2018
Actual enrolment:	12

URL result
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

Internal documents
File