AIR (Artificial Implant to Restore the medial meniscus function)2 clinical investigation

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19974

Source
NTR

Brief title
AIR2

Health condition

post-meniscectomy pain

Sponsors and support

Primary sponsor: Atro Medical B.V.
Source(s) of monetary or material Support: Loan and venture capital

Intervention

Outcome measures

Primary outcome

Performance of the Trammpolin® medial 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 secondary endpoints will be analyzed from the participant data collected from this clinical investigation: KOOS Pain sub scale, KOOS overall scale, VAS, Oxford Knee Score, EQ-5D health utility, WORQ, Patient satisfaction, Knee X-ray, Knee MRI, biopsy at implantation.

Study description

Background summary

The objective of the clinical investigation is to evaluate the safety and performance of the Trammpolin® medial meniscus prosthesis and to demonstrate that the Trammpolin® medial meniscus prosthesis is able to restore the function of the natural meniscus to provide pain relief in the medial compartment of the meniscus-deficient knee.

Study objective

The Trammpolin® medial meniscus prosthesis is intended to restore the function of the natural meniscus to provide unicompartmental pain relief in the meniscus-deficient knee and redistributes the loads transmitted across the knee joint.
The ability to restore the function of the natural meniscus to provide pain relief will be assessed by evaluation of the performance of the Trammpolin® medial meniscus prosthesis in improving pain as assessed by the KOOS Pain Sub-scale at 24 months post-operative compared to baseline (pre-operative).

Study design

Screening visit (V1), Surgery (V2), Follow up visits will be done at 2 weeks, 6 weeks, 3 months, 6 months, 12 months, and 24 months after surgery.

Intervention

Screening visit (V1), Surgery (V2), Follow up visits will be done at 2 weeks, 6 weeks, 3 months, 6 months, 12 months, and 24 months after surgery.

Contacts

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Eligibility criteria

Inclusion criteria

1. Has medial compartment knee pain and had a medial partial or total meniscectomy > 6 months ago. The lack of meniscus tissue is confirmed by patient history and MRI
2. Has a KOOS Pain of ≤ 75 (100 being no pain and the highest attainable score)
3. Is between age 18 and 70 years (inclusive) at the time of screening
4. Has neutral alignment ± 5° 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® medial meniscus prosthesis
6. Is willing and able to comply to the clinical investigation required follow up visits, questionnaires, X-rays and MRI's
7. Is able and willing to understand and sign the clinical investigation 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 potentially 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® medial meniscus prosthesis
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 > 5° 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 > 30 at the time of screening
12. Has a knee flexion contracture > 10°
13. Has a knee flexion < 90°
14. Had a previous High Tibial Osteotomy (HTO) < 1 year ago
15. Has insufficiency fractures or avascular necrosis of the medial compartment
16. Has an active infection or tumor (local or systemic)
17. Has any type of knee joint inflammatory disease including Sjogren's syndrome
18. Has neuropathic knee osteoarthropathy, also known as Charcot joint
19. Has any medical condition that does not allow possible arthroscopy of the knee
20. Has neurological deficit (sensory, motor, or reflex)
21. Is currently involved in another investigation of the lower extremity
22. Anticipates having another lower extremity surgery during the clinical investigation period
23. Has received any corticosteroid knee injections ≤ 3 months prior to surgery
24. Has proven osteoporosis
25. Is on immunostimulating or immunosuppressing agents
26. 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)
27. Is a female who is lactating, expecting, or is intending to become pregnant during the clinical investigation period
28. Is mentally incapacitated (incapable of appraising or controlling conduct) or have mental disability (e.g., dementia or Alzheimer's)
29. Has a condition or be in a situation that, in the Investigator's opinion, may confound the clinical investigation results, may risk the safety of the patient, or may interfere significantly with the subject's participation in the clinical investigation

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-10-2021
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-10-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54484
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9805
CCMO	NL75393.000.21
OMON	NL-OMON54484

Study results