Feasibility of the Artimis*medial meniscus prosthesis intended to restore the medial meniscus function to provide pain relief after meniscectomy

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The objective of the clinical investigation is to evaluate the safety and performance of the Artimis* medial meniscus prosthesis system and to demonstrate that the Artimis* medial meniscus prosthesis is able to restore the function of the natural...

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

Summary

ID

NL-OMON54484

Source
ToetsingOnline

Brief title
AIR (Artificial Implant to Restore the medial meniscus function)2

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: Jointpain, Meniscus, Osteoarthritis, Prosthesis

Outcome measures

Primary outcome

Performance of the Artimis* 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

Secondary endpoints:

• KOOS Pain Sub-scale at 6 weeks, 3 months, 6 months and 12 months post-operative compared to baseline (pre-operative).

• KOOS overall scale at 6 weeks, 3 months, 6 months, 12 months and 24 months post-operative compared to baseline (pre-operative).

• Visual Analog Scale (VAS) Pain 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).

• Oxford Knee Score (OKS) at 6 months, 12 months and 24 months post-operative compared to baseline (pre-operative).

• EuroQol-5D-5L health utility score at 6 months, 12 months and 24 months post-operative compared to baseline (pre-operative).

• Work, Osteoarthritis and joint-Replacement Questionnaire (WORQ) at 6 weeks, 3 months, 6 months, 12 months and 24 months post-operative compared to baseline

(pre-operative).

• Patient satisfaction on a 5-point Likert scale at 6 months, 12 months and 24 months post-operative compared to baseline (pre-operative).

• Knee X-ray at 12 months to evaluate the height of the joint space compared to baseline (pre-operative).

• Knee MRI at 6 and 24 months after surgery to evaluate the cartilage damage compared to baseline (pre-operative) and amount of extrusion of the Artimis*medial meniscus prosthesis.

• Biopsy of synovial fluid and synovium to evaluate foreign body reaction in the knee when the device is explanted (if applicable) compared to surgery.

Safety endpoints:

• The nature and frequency of all adverse events observed during the clinical investigation including their timing, severity and relatedness to the investigational device and/or procedure.

• Incidence of secondary surgical intervention of the index knee.

Study description

Background summary

Meniscal tears are the most common knee injury, resulting in approximately 61 meniscectomies per 100,000 patients annually [1]. In the Netherlands, in 2010, approximately 42,000 meniscectomies were performed annually and, in the US, approximately 500,000 patients are subject to partial or total meniscectomy. Meniscectomy results in impaired function of the meniscus and decreases the contact area by up to 75% and increase contact pressures by up to 300% [2]. Clinical and radiological studies have shown that most patients improve clinically post-meniscectomy, but that partial or complete loss of the meniscus

promotes in 40% of the post-meniscectomy patients the early development and progression of Knee Osteoarthritis (KOA) 5-20 years post-surgery [3]. KOA is a chronic joint disease that results from breakdown of joint cartilage and the underlying bone. The most common symptoms of KOA are chronic joint pain, stiffness and swelling of the knee. Chatain, et al. [4] outlines that 14% of these post-meniscectomy patients demonstrates the rapid onset of symptomatic unicompartmental pain in the meniscus-deficient knee, the so-called post-meniscectomy pain syndrome.

As no cure for the post-meniscectomy pain syndrome patient is currently available, most patients endure the remaining pain and experience gradual loss of their mobility. Therefore, patients have to adapt their daily life activities. The disease symptoms often have a profound effect on the quality of life (QoL), affecting both physical functioning and psychological parameters. There are no specific clinical guidelines for the post-meniscectomy pain syndrome and therefore these patients suit best in the osteoarthritis guidelines and are treated likewise. In these knee osteoarthritis guidelines [5] the Standard of Care (SOC) treatment scheme is as follows:
• First line of treatment is a combination of non-pharmacological interventions such as exercise, education and weight loss programs, physical therapy and use of assistive devices. During this stage of the disease, physicians often recommend soft pain medication, such as paracetamol.
• Second line of treatment involves stronger pain medication, such as nonsteroidal anti-inflammatory drugs (NSAIDs) and the even less-desirable opioids. Also, corticosteroid injections are applied directly into the knee joint. These treatments reduce pain but do not prevent continuous joint degeneration. This will eventually result in a more severe KOA, for which pharmacological pain intervention is no longer sufficient. With a mean age at KOA diagnosis of 54 years-old, the average time on pain medication preceding the third line of treatment is 13 years for the regular patient (K/L grade 2) [8].
• Third line and final treatment: once most articular cartilage is degenerated and first- and second-line conservative therapies are no longer effective to delay or prevent disease progression, surgical treatment is often necessary. The SOC surgical treatment for end-stage KOA is Total Knee Arthroplasty (TKA) or Unicompartmental Knee Arthroplasty (UKA). This highly invasive surgical intervention removes the diseased bone and cartilage from respectively one or both knee joint compartments, which is replaced with an artificial joint made of synthetic materials. TKA have demonstrated improved function, reduced pain and improved QoL for patients [9]. For ease of reading, TKA and UKA are grouped as *TKA* in the remainder of this document, unless specifically indicated separately. A distinct limitation of TKA is that it is a suboptimal treatment option in patients under the age of 65 years since younger active and high-demand patients are at a greater risk for prosthesis failure due to reduced durability of the TKA. Consequently, the patients are likely to outlive their prosthesis and a revision surgery is required to replace the original implant with a new knee replacement. This is a more complex procedure

associated with higher complication rates, extended hospitalization, and unsatisfactory functional outcomes [10]. After the revision TKA no other treatment options are possible, leaving the patient immobile and wheelchair bound when the prosthesis stops functioning.

The development of the Artimis*medial meniscus prosthesis focuses on those post-meniscectomy pain syndrome patients, with limited underlying cartilage damage (Kellgren Lawrence scale 0-3), who remain with unicompartmental pain in the medial meniscus-deficient knee and reduced mobility. This is the patient group that spend on average 13 years on a non-surgical regimen of pain medication [8]. Treatment options for patients with meniscus deficient knees are limited to transient conservative treatment options (i.e., first and second line of treatment of SOC). This treatment often falls short, and the pain remains on an unacceptable level in many patients. Furthermore, in a meniscus deficient knee the KOA progresses till it reaches end-stage KOA condition, then the only solution is a TKA whereby the degenerative (part of the) joint is removed and replaced. There is a large treatment gap between the first knee pain after meniscectomy and the eligibility for a TKA. Hence, there is a strong unmet need for a durable and cost-effective treatment solution that will relieve chronic knee pain and regain mobility in symptomatic post-meniscectomy patients. Such treatment could save the knee joint and delay or prevent the need for a knee joint replacement.

The Artimis* medial meniscus prosthesis is intended to restore the function of the natural meniscus to provide unicompartmental pain relief in the meniscus-deficient knee. The Artimis* medial meniscus prosthesis is intended to restore the function of the natural meniscus and redistributes the loads transmitted across the knee joint.

Study objective

The objective of the clinical investigation is to evaluate the safety and performance of the Artimis* medial meniscus prosthesis system and to demonstrate that the Artimis* 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 design

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

Intervention

The implantation of the meniscus prosthesis and fixation tape and anchoring screws is conducted by means of an arthroscopic procedure, minimizing the

surgical damage to the joint. A regular arthroscopic inspection is performed through two portals in the skin and capsule on the anterior side of the knee. The lateral portal provides access for the camera and the medial portal for the surgical instruments. The surgical technique is described in CIP section 2.9.

Study burden and risks

The present clinical investigation represents the second prospective clinical evaluation in humans of the Artimis* medial meniscus prosthesis. The first design of the Artimis* medial meniscus prosthesis has been evaluated in a previous feasibility (First in Man, AIR clinical investigation, AM-001) clinical investigation, which has been prematurely stopped due to the occurrence of serious adverse device effects. Based on the learnings from this clinical investigation, ATRO Medical has improved the design of the Artimis* medial meniscus prosthesis and confirmed the functionality of the device by extensive in-vitro testing. ATRO Medical can confirm that any potential risk presented by this clinical investigation has been minimized by in-vitro testing, appropriate product design and through use training. ATRO Medical can confirm that any potential risk presented by this clinical investigation has been minimized by in-vitro testing, appropriate product design and through use training. Based on this data, we anticipate the clinical benefit of the Artimis* medial meniscus prosthesis may include:
• Pain relief in the medial compartment of the knee
• Increased functional activity
• Symptom relief
• Improved Quality of Life

The following potential Anticipated Adverse Device Effects (AADEs) may arise as a result of implanting the investigational device:
• Pain discomfort and/or Range of Motion (RoM) impairment, caused by oversizing, undersizing or wrong placement of the meniscus prosthesis
• Pain discomfort and/or RoM impairment, caused by impingement of the meniscus prosthesis
• Breakage of the meniscus prosthesis, potentially leading to pain discomfort and requiring consecutive surgery to remove or replace the prosthesis
• Wear of the meniscus prosthesis, potentially leading to breakage, pain discomfort and/or synovitis
• Wear of the TLS® tape, potentially leading to breakage and/or synovitis
• 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 knee joint structures and tissues.
• Neurovascular damage during the procedure: The drilling of the posterior drill hole may damage the neurovascular structures posterior in the knee (popliteal nerve, artery and vein)

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. 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 Artimis* 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 Artimis* 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)
30. 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

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	08-03-2022
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Artimis meniscus prosthesis
Registration:	No

Ethics review

Approved WMO

Date:	01-09-2021

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-11-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-04-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-11-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-04-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-08-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-10-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Not approved Date:	14-11-2024
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

ID: 19974
Source: NTR
Title:

In other registers

Register	ID
ClinicalTrials.gov	NCT05297175
CCMO	NL75393.000.21