The VENUS (Verifying the Effectiveness of the NUsurface® System) Clinical Study

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The rationale for performing this clinical study is to gather clinical data to evaluate the safety and effectiveness of the NUsurface device compared to the Standard of Care.

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

Summary

ID

NL-OMON46974

Source
ToetsingOnline

Brief title
VENUS study

Condition

- Joint disorders

Synonym
medial meniscus deficiency, medial meniscus torn

Research involving
Human

Sponsors and support

Primary sponsor: Active Implants LLC
Source(s) of monetary or material Support: Active Implants LLC

Intervention

Keyword: Medial Meniscus, Meniscally deficient Knee, NUsurface Meniscus Implant

Outcome measures

Primary outcome

The primary endpoint components of the study are as follows:

Effectiveness:

The KOOS Pain Subscale and KOOS Overall Scale (Average of the 5 KOOS Subscales)

relative to baseline * at 24 months

Investigational Group Device-Related Secondary Surgical Interventions: The

device related secondary surgical interventions of the NUsurface®

Meniscus Implant during the 24 month post-operative period.

Control Group Post-InterventionTreatment Surgical Procedures: The treatment

failures of the control group are defined as any surgery on

the index knee medial compartment up to and including 24 months.

Each of these components of Overall Success will be analysed separately, but

their analyses will not affect the 0.05 type I error rate (threshold p-value of

0.05 for significance) for the test of the primary superiority hypothesis.

Secondary outcome

Secondary Data Elements:

Safety:

Adverse events in either Group occurring at a rate of 5% or more at any post-treatment follow-up period will, if applicable, be statistically compared between study groups. Examples of safety measurements are:

1. Incidence of all adverse events through the 1.5, 3, 6, 12, and 24-month post-treatment period.
2. Incidence of secondary (or primary for the non-surgical control patients) surgical intervention through the 1.5, 3, 6, 12, and 24-month post-treatment period.
3. Device-related complication is defined as a complication found to be caused by the device and device malfunctions (including severity), as assessed at each post-op period. Device malfunctions include dislocation, device fracture, and/or removal (and infection, if related to device).
4. Non-surgical Control Post-Treatment Procedures: Treatment failures of the control group defined as any post-intervention surgical procedure of the index medial knee compartment.

Study description

Background summary

Tears of the meniscus are a common source of knee pain. Clinical assessment of meniscus tears includes nonoperative and operative treatment options. Non-operative treatment includes physical therapy, bracing, rest, activity modification, analgesics, and inflammatory

reduction measures such as icing, non-steroidal anti-inflammatory medications and occasionally corticosteroid injections.
Non-operative treatment is usually instituted and followed for approximately six weeks, and patients typically return
to full activities after three months. If the patient does not improve, then surgery must be considered.

Operative treatment includes menisci tears repairs to relief pain through tear resection or repair while preserving as much of the meniscus as possible. Allograft implantation*` with primary indication for the surgery being A sympyomatic patient having undergone a previous meniscectomy with persistent pain in the involved compartment and who has failed non-operative treatment. Other operative treatment are meniscal scaffolds and Interpositional devices. Each of the above treatment options has limitations.

The majority of the aforementioned treatment options are designed primarily to treat younger patients, most often suffering from traumatic tears rather than degenerative tears that are most common in people 35 years old and above. Because of poor regenerative capabilities usually found in these patients, surgeons are unlikely to choose any of these treatment options. On the other hand, more aggressive procedures like Unicompartmental Knee Arthroplasty or Total Knee Arthroplasty may fit in a more severe condition of the cartilage, e.g., grade 4 OB and relate to older patients (60+), that in many cases, have three-compartmental disease. Thus, a *treatment gap* can be defined between the twoapproaches .
Active Implants strongly believes that the NUsurface® Meniscus Implant can be the preferred treatment that will meet the significant demand from this patient population in the *treatment gap.*

The NUSurface® implant received CE mark in March 2008 and has been used since in Belgium, Italy, Israel and The Nederlands. It is an implant made of medical polymeres and designed to replace the damaged meniscus in the knee.

Study objective

The rationale for performing this clinical study is to gather clinical data to evaluate the safety and effectiveness of the NUsurface device compared to the Standard of Care.

Study design

A multi-centered, prospective, randomized, interventional, superiority study

Intervention

Patients will be randomized to receive either the NUsurface Meniscus implant,or

be treated with the non-surgical Standard of Care.

Study burden and risks

The burden for the patients is that they have to undergo a more extensive post operative follow up and rehabilitation progam compared to standard patients outside this study (including questionnairres).

The possible risks of this study are risks associated in general in kneesurgeries, risks specific for orthopaedic knee implants and additional risks (see E9)

The risks associated with NUsurface®:
The expected life of meniscal implant is difficult to estimate. These components are made of foreign materials which are placed within the body to help with the potential restoration of mobility and/or the reductionn of pain. However, because of the many biological, mechanical and physicochemical factors which affect these devices, the components cannot be expected to withstand the loads of normal healthy meniscus indefinitely.

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

Inclusion Criteria: In the opinion of the investigator, if ALL of the following 8 conditions are applicable for the index knee, then the patient is included if he/she: ;1. Had > 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 no pain)
3. Is between age 30 and 75 years (inclusive) at the time of study treatment
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
5. Has * 2 mm intact medial meniscal rim capable of being fitted with a NUsurface® device AND is also recommended for the baseline non-surgical (and, if likely to receive benefit, any injection)
therapies to be administered in the study.
6. Is willing to be entered into either arm of the study: implanted with the NUsurface device OR
treated with the recommended control arm therapies.
7. Is able to do the study required follow up visits, questionnaires, X-rays, and MRI*s
8. Is able and willing to understand and sign the study Informed Consent Form
9. Is able to read and understand the national language of the country in which the relevant clinical site is located

Exclusion criteria

Exclusion Criteria: If ANY of the following 35 conditions are applicable, then the patient is excluded if he/she:;1) Has a symptomatic knee because of a tear that could be addressed by a repeat partial
meniscectomy leaving > 4 mm of medial meniscus rim
2) Has evidence of a Outerbridge Grade IV cartilage loss on the medial tibial plateau or femoral
condyle that potentially could contact a NUsurface implant (e.g., a focal lesion > 0.5 cm correlating to a circular defect of > 8 mm in diameter)
3) Has complete disruption of the posterior root attachment of the meniscus
4) Has lateral compartment pain and Grade III or Grade IV Outerbridge cartilage score in the lateral
compartment

5) Has a varus or valgus knee deformity > 5º requiring a tibial or femoral osteotomy
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 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 study treatment
11) Has a BMI > 32.5 at the time of study treatment
12) Decides to receive (if eligible and an option) allograft medial meniscus transplantation
13) Received any type of prosthetic knee implant made of artificial non-resorbable plastic, metal or
ceramic, not including the NUsurface® Meniscus Implant
14) Has a knee flexion contracture > 10º
15) Has flexion < 90º
16) Had a previous medial femoral condyle surgery (not including microfracture) or High Tibial
Osteotomy (HTO)
17) Has insufficiency fractures or avascular necrosis of the medial compartment
18) Has an active infection or tumor (local or systemic)
19) Has any type of knee joint inflammatory disease including Sjogren*s syndrome
20) Has neuropathic knee osteoarthropathy, also known as Charcot joint
21) Has any medical condition that does not allow possible arthroscopy of the knee
22) Has neurological deficit (sensory, motor, or reflex)
23) Is currently involved in another investigation of the lower extremity
24) Anticipates having another lower extremity surgery during the study period
25) Is contraindicated for hyaluronic acid injections (i.e., patients with known hypersensitivity [allergy] to hyaluronan [sodium hyaluoronate] preparations); patients having knee joint infections or skin diseases or infections in the site of possible injections
26) Is contraindicated for corticosteroid injections (i.e., patients with allergy to any of the components or with idiopathic thrombocytopenic purpura)
27) Has received any corticosteroid knee injections * 3 months prior to study treatment
28) Has chondrocalcinosis
29) Is on immunostimulating or immunosuppressing agents
30) 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)
31) Is a female who is lactating, expecting, or is intending to become pregnant during the study
period
32) Is an active smoker
33) Is mentally incapacitated (incapable of appraising or controlling conduct) or have mental

disability (e.g., dementia or Alzheimer*s)
34) Is a prisoner
35) Is a patient who has economic incentive not to improve

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-11-2014
Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	NUsurface® meniscus implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-04-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-06-2015

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-09-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL47116.068.14
Other	nog niet bekend

Study results

Date completed:	01-11-2018
Actual enrolment:	14