Evaluation of the Latella Implant System for Lateralization of the Iliotibial Band to Offload the Medial Condyle for Pain Relief in Patients with Medial Osteoarthritis * A Safety Study

Published: 19-08-2013
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The objective of this study is to evaluate the safety and technical feasibility of the Latella Implant in the treatment of patients with medial osteoarthritis of the knee.

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

Summary

ID

NL-OMON41663

Source
ToetsingOnline

Brief title
COTERA-1

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
arthritis on the inner side of the knee, Medial osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Cotera, Inc.
Source(s) of monetary or material Support: Cotera Inc.

Intervention

Keyword: Latella Implant, Medial Osteoarthritis, Pain Relief

Outcome measures

Primary outcome

Safety is the primary endpoint of this clinical investigation and will be evaluated by:

* Freedom from unanticipated serious device related adverse events up to 12 months after implantation surgery

* Freedom from radiographic evidence of screw loosening up to 12 months after implantation surgery.

NOTE: This does not include natural disease progression.

Secondary outcome

Performance (technical feasibility) is the secondary endpoint of this clinical investigation and will be evaluated as the ability of the Latella Implant to be placed under the iliotibial band and fixed to the distal, lateral aspect of the femur.

Additional exploratory outcome measures are:

1. Patient Reported Outcome scoring of joint specific, disease specific and general Quality of Life measures using:

* Knee injury and Osteoarthritis Outcome Score (KOOS)

* International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form

* 36-Item Short Form Health Survey (SF-36) administered by either the RAND 36 Item Short Form Health Survey (SF-36 specific form) or by the IKDC Current Health Assessment Form, which includes the SF-36 questions

* Patient Global Assessment (PGA)

* Anterior Knee Pain Scale (Kujala)

2. Radiographic analysis to evaluate :

* Joint space width (comparison between baseline and 3, 6, 12 and 24 months post implantation)

* Development of ectopic calcification post implantation

* Patellar tracking via skyline view. Intra-operative images only, follow-up imaging will be performed by MRI

* Standing axis view of leg to determine varus angle and to see if alignment shifts from pre-operative to 3 months post implantation

3. MRI analysis to evaluate:

* Meniscal extrusion

* Articular cartilage morphology

* Subarticular marrow edema

* Subarticular bone attrition

4. Three-Dimensional Gait Analysis to evaluate:

* Adduction moment

* Toe-out angle

Study description

Background summary

Knee Osteoarthritis (OA) afflicts over 15M individuals in the US. OA is sometimes referred to as degenerative, or wear and tear, arthritis. It is a progressive degenerative disease characterized by the breakdown of articular cartilage. Over time, the cartilage may wear away entirely, resulting in bone-on-bone contact, resulting in joint pain and stiffness. Since bones, unlike cartilage, have many nerve cells, direct bone contact can be very painful to the OA sufferer. In addition to the pain and swelling, the OA sufferer can experience a progressive loss of mobility at the knee joint. This is due to loss of the joint space, where the articular cartilage has completely worn away.

OA usually affects the side of the knee closest to the other knee (called the medial compartment) more often than the outside part (the lateral compartment). OA in the medial compartment can lead to bowing of the knee. A bowlegged posture places more pressure than normal on the medial compartment. The added pressure leads to more pain and faster degeneration where the cartilage is being squeezed together. Knee OA is typically caused by excessive mechanical load on the medial condyle.

Treatment for medial knee OA relies on unloading the medial condyle by shifting the load back towards the midline of the knee. Current therapy includes exercise, weight loss, external bracing, internal and external surgical mechanical distraction and tibial osteotomy. Current surgical treatment are either limited in their efficacy or are very invasive. Hence, there is room for improvement in the treatment of patients with knee OA.

Cotera has developed a novel device, the Latella Implant, to provide patients with a low invasive treatment alternative for early to mid-stage OA. The Latella Implant has the potential to not only reduce joint pain but it may also slow down the progression of OA. Furthermore, the ease of manufacturability of the novel device and the minimal invasiveness of the surgical procedure would make this treatment cost effective relative to the current surgical options.

Study objective

The objective of this study is to evaluate the safety and technical feasibility of the Latella Implant in the treatment of patients with medial osteoarthritis of the knee.

Study design

Prospective, non-randomized, single-arm, multi-centre study

Intervention

Medical device: Latella Implant

Surgery: Implantation of the Latella Implant during a surgery. Incision will be about 5 cm.

Study burden and risks

After the implantation surgery, the patients will be asked to return for 9 post-operative hospital visits (at 2 weeks and 3, 6 ,12, 18, 24, 36, 48 and 60 months after surgery). According to the investigators of the Slotervaart Hospital, the number of visits is comparable to similar type of treatments of the knee. Therefore, the number of follow-up visits is thus not considered as an extra burden for the patients. However, the patients are being asked to complete 5 questionnaires (KOOS, IKDC,SF36, PGA and Kujala) at baseline, 3, 6, 12, 18, 24, 36, 48 and 60 months follow up visits. The investigators consider 6 X-rays as non-standard of care, being the radiograph at baseline and 24 months to determine the minimal joint space width, the X-rays at 36, 48 and 60 months to determine screw loosening and ectopic calcification and an X-ray of the standing axis view at 3 months after surgery. In addition, all MRI assessments (at baseline and 6, 12 and 24 months post-op) are considered as not standard of care by the investigators. Also, the patient is asked agree to do gait analysis at screening and 3 and 12 month visit. The gait analysis assessments are optional. The burden of the hospital visits and the examinations during these visits are considered similar to that of other orthopedic clinical trials, and are necessary to evaluate the candidate technology and ensure subject health and safety.

Literature shows that there are no less-invasive surgical options available for patients with significant knee pain. After conservative care has failed, the only option prior to knee replacement for patients today is high tibial osteotomy (HTO). The anticipated clinical benefit of the use of the Latella Implant is to relieve knee pain and to improve knee function of patients suffering from medial osteoarthritis in the knee, thereby improving the subject*s quality of life. It may also reduce the rate of disease progression. The Latella Implant is not expected to halt or reverse disease progression. Eventual removal of the device and future treatment with more invasive surgical

intervention is expected. While the durability of the effect is yet unknown, it may be expected to approach that of tibial osteotomy, which can exceed five years.

The Latella-specific risks are described in section E9/E9a. These risks are considered to be comparable to the risks related to HTO.

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. History of pain diagnosed as due to medial osteoarthritis with failure of pain relief from non-operative therapy
OR failure of pain relief 6 months post arthroscopic treatment for medial osteoarthritis (see exclusion criteria for excluded procedures)
2. Age: 30 * 65 years
3. Weight: Less than 110 kg
4. Kellgren-Lawrence scores: Grades 2-3
5. Willing and able to understand and sign the informed consent

Exclusion criteria

* Varus angle > 10 degrees
* Osteoporosis
* Rheumatoid arthritis
* Immunosupressive disorders, for example, diabetes
* Chronic steroid use
* History of heterotopic ossification
* Ligament instability
* Joint instability
* Capsule contracture
* Ligament contracture
* Radiologic evidence of patellar osteoarthritis which in the opinion of the treating physician would preclude enrollment
* History of patellar instability including: Subluxation, Dislocation, Maltracking, Excessive anterior knee pain
* Radiologic evidence of lateral osteoarthritis
* Post-traumatic osteoarthritis
* Lateral osteophytes that would underlie implant region (diagnosed via x-ray)
* Free floating bodies
* Prior surgery or trauma in or near the intended implant site which would create scar tissue and interfere with the implant surgery.
o NOTE: Partial medial meniscectomy will be allowed
* Prior anterior cruciate ligament reconstruction
* Tight Illiotibial Band or Illiotibial Band Syndrome
* Femoral or tibial bone deformity
* Bone metabolic disease not associated with osteoarthritis
* Disease affecting the connective tissue or muscle
* Continued participation in contact sports
* Less than 5 year history free of lung, colorectal, breast, thyroid, prostate, or kidney cancer
* Less than 5 year history free of primary bone tumors
* History of stroke, upper limb or lower limb motor disorders
* Bleeding diathesis

* Chronic use of anticoagulants
* Metal ion allergy
* Absolute or relative contraindication for MRI
* No fixed abode
* Substance abuse (drug or alcohol)
* For women of childbearing potential: pregnant, or willing to become pregnant during the course of the clinical investigation
* Have been exited from in another clinical study less than 30 days prior to enrollment in this clinical study, currently participating in another clinical study or plan to be enrolled in another clinical study during the course of this study.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-11-2013
Enrollment:	9
Type:	Actual

Medical products/devices used

Generic name:	Latella Implant
Registration:	No

Ethics review

Approved WMO

Date:	19-08-2013
Application type:	First submission

Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	20-08-2013
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	02-10-2013
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	31-10-2013
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	12-02-2014
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	15-05-2014
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	17-02-2015
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	03-12-2015
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL44476.048.13

Study results

Date completed: 05-04-2017

Actual enrolment: 10

Summary results
Trial is onging in other countries