Global, Prospective, Multi-Center, Non-randomized, Controlled Non-inferiority Trial to Evaluate Symptom Relief in Patients with Medial Knee Osteoarthritis (OA) Treated with the KineSpring® Knee Implant for Load Reduction Compared to High Tibial Osteotomy (HTO)

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The primary objective of the study is to demonstrate non-inferiority of the KineSpring System, when compared to standard HTO surgery in improving pain and function outcomes at 24 months in patients with primarily unicompartmental medial knee...

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

Summary

ID

NL-OMON41373

Source
ToetsingOnline

Brief title
GOAL Trial
Protocol No: KINE-1101

Condition

- Joint disorders

Synonym

degenerative joint disease, Osteoarthritis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: arthritis, KineSpring, Knee osteoarthritis, Knee pain

Outcome measures

Primary outcome

A patient will be declared a clinical efficacy success if all of the following

conditions are met at the 24-month follow-up:

1. Clinically significant improvement of at least 20% from baseline for the

WOMAC pain severity subscale with an absolute change of >=10 points.

2. Clinically significant improvement of at least 20% from baseline for the

WOMAC function subscale with an absolute change of >=10 points.

3. Maintenance of normal range of motion, defined as: a) knee flexion >=90 -

<=150 degrees, and b) knee extension within 10 degrees of the *neutral* or zero

degree position

4. No subsequent surgical intervention of the medial compartment of the treated

knee (including device failures requiring removal or revision); and no serious

device-related adverse events or device failures.

5. Maintenance of device integrity as evaluated by radiographic assessment.

Secondary outcome

Secondary Effectiveness Endpoint:

Clinical outcomes will be determined using the following outcome measurement tools:

• To evaluate symptom severity changes from baseline measurement for each of the following outcome measures at each follow-up visit:

o Knee Injury Outcomes Scores (KOOS) including WOMAC Pain, Stiffness and Function Scores

o Knee Society Knee and Function Scores

o Knee range of motion as measured by degrees of flexion and extension

o Pain severity using the knee specific pain severity score (VAS)

o Patient assessment of global status

o High Arthroplasty Activity Score (HAAS)

o Generic health status using the EQ-5D

Radiographic outcomes will be evaluated using the following measurements:

• Kellgren-Lawrence OA classification

• OARSI Radiographic Altlas OA Score

• Device evaluation

Safety Endpoints:

Safety outcomes will be determined by evaluating by the type, frequency, severity, and relatedness of adverse events through the 24-month timepoint for all subjects.

Endpoints will be evaluated at 3, 4, and 5 years for the KineSpring arm in

addition to the timeframes specified above.

Study description

Background summary

Osteoarthritis affects an estimated 15% of the world*s population2. Knee OA is the most predominant form, and approximately 90% of symptomatic patients present primarily with medial compartment knee OA2-5. The prevalence of OA will continue to rise with the increasing age and increasing lifespan of the population. This condition decreases functional independence and in some instances may impair the afflicted individual*s ability to complete normal activities of daily living or participate in age-appropriate recreational activities. Patients face progressive pain and disability for the remainder of their lives. In spite of the prevalence and the extensive study of the disease, no cure for OA has yet been identified.

The evidence implicating joint loading, and more specifically joint overloading, in the OA process is well documented in the literature. Joint overloading correlates to incidence, symptom severity, radiographic, morphologic and biological processes. Load modifying treatments including weight loss, valgus braces, HTO, external distraction devices clearly demonstrate symptom relief*pain reduction and improved function. Despite these positive results both physicians and patients are frustrated with the inconsistent outcomes from these treatment options.

Given the increasing prevalence of OA in younger patients and the evident potential of load management to positively impact these patients, the pursuit of novel and innovative load modifying therapies that overcome the limitations of the current treatment options is both warranted and necessary.

The KineSpring System is expected to provide a clinically beneficial reduction of load on the diseased surface within the knee, by acting as an extra-articular supplemental load path to the affected joint. Additionally, the KineSpring System has no known detrimental effect on natural knee kinematics since it is implanted via relatively small incisions without disrupting bone, cartilage, or ligaments. Important advantages of the KineSpring System, especially for patients who want to remain active and healthy, include the potential for quick postoperative recovery and joint mobility, and the ability to preserve natural joint anatomy so that future surgical options remain open for the patient

Study objective

The primary objective of the study is to demonstrate non-inferiority of the KineSpring System, when compared to standard HTO surgery in improving pain and function outcomes at 24 months in patients with primarily unicompartmental medial knee osteoarthritis.

Study design

This study is designed as a multi-center prospective, non-randomized, non-inferiority, two-arm, active concurrent, controlled trial. Up to 30 sites will enroll a minimum of 225 subjects and maximum of 450 subjects in a 2:1 ratio (KineSpring to HTO). Patients (subjects) who have been diagnosed with symptomatic osteoarthritis primarily in the medial compartment of the knee will be enrolled concurrently into either the KineSpring arm or HTO surgical arm.

The test arm will consist of a minimum of 150 subjects and a maximum of 300 subjects who are implanted with the KineSpring device. The control group will consist of a minimum of 75 subjects and a maximum of 150 subjects who will undergo HTO surgery for the treatment of symptoms associated with medial knee OA. There will be no adjustment to the sample size due to loss of follow-up. The adaptive sample size is based upon the number of patients required to provide assurance of safety and effectiveness using the concurrent control and allowing for 15 percent loss to follow up.

Follow-up visits and examination will occur for all patients at 6 weeks, and 3, 6, 12 and 24 months post-enrollment to collect data for the primary evaluation of safety and effectiveness with annual follow up thereafter for the KineSpring patients only.

At each follow-up visit, subjects will be interviewed to determine if adverse events (AEs) were experienced since the previous follow-up visit. A complete orthopaedic knee assessment will be performed at baseline for all subjects and again during each follow-up. All subjects will be required to complete WOMAC, KOOS, knee pain severity score and global assessment, HAAS, and EQ-5D to evaluate, disability, function, pain, and quality of life at each follow-up visit.

Radiographic evaluations will be performed at baseline, discharge, and 3, 12, and 24 months for all patients and at 5 years post-operatively for KineSpring patients.

Intervention

The KineSpring System (Moximed, Hayward, CA, USA) is a CE Marked extra-capsular knee implant that consists of titanium alloy femoral and tibial bases, and a cobalt/cobalt chrome alloy absorber that reduces the load transferred to the diseased medial compartment of the knee joint. The

KineSpring System is implanted through two medial incisions, one on the distal femur and one on the proximal tibia. The femoral and tibial bases are secured to the femur and tibia, respectively, using bone screws. The absorber consists of central spring elements that provide compressive load absorption and an articulating ball and socket joint at each end that allow the device to accommodate the natural motions of the knee. The absorber is connected to the femoral and tibial bases and implanted in the subcutaneous tissue of the medial extra-capsular space. The KineSpring System remains extra-articular.

Study burden and risks

The potential risks for subjects implanted with the KineSpring System enrolled in the trial include 1) those related to any invasive surgery 2) risks associated with orthopedic knee implants, 3) risks associated with radiography. In addition, there is always a chance that unforeseen risks may also occur.

Risks associated with general surgery include:
• adverse reactions to anesthesia (neurological, cardiac and respiratory deficit)
• blood loss, blood vessel damage, phlebitis or hematoma
• blood transfusion which may cause circulatory collapse, blood incompatibility, kidney damage, hepatitis, infection with HIV
• myocardial infarction
• deep vein thrombosis, pulmonary embolism or thrombus formation in other vessels
• stroke
• fever
• pneumonia
• respiratory distress
• injury to muscle, soft tissues or nerves
• wound swelling, draining or delayed healing
• pain and rehabilitation associated with recovery from surgery
• inability to perform certain tasks, such as lifting, exercising etc.
• death

Risks associated with orthopedic knee implants:
• Implant malposition resulting in mechanical failure, device loosening, or lack of efficacy
• Mechanical failure of the device or components
• Implant may fail mechanically (loosen, deform, disassemble, disarticulate, break, fatigue or migrate) which may necessitate another surgery
• Wear debris that may cause irritation or tissue reaction
• Allergies to implant materials or foreign body reaction
• Failure of implant to improve symptoms and/or function
• Infection may necessitate another surgery to treat the infection
• Irritation or inflammation to the surrounding tissues that may result in

discomfort, synovitis or bursitis
• Damage to or compromise of adjacent neurovascular structures, lymphatic structure, or ligaments
• Insufficient or limited range of motion of the knee
• Potential for bone loss or fracture
• Overloading of the lateral compartment
• Pain, stiffness or swelling of the knee
• Stitch abscess
• Allergic reaction to suture/dressing
• Cellulitis
• Keloid like scar formation
• Hematoma
• Knee scarring, arthrofibrosis, or periprosthetic local adhesions
• Audible clicking, squeaking, or other noise may be associated with the KineSpring device

Some of the complications may lead to subsequent surgical intervention for revision, removal, reoperation or other surgical intervention. This list of risks is not an exhaustive list and it is understood that any or all risks are possible.

Risks Associated with Radiographs:
The series of radiographs required for this study are similar to routine knee surgery radiographs and will expose the subject to small doses of radiation. The maximum estimated x-ray exposure over the course of the study is about 0.135 mSv or 13.5 mrem. This is approximately equivalent to a uniform whole body exposure of 16.4 days (0.045 years) of exposure to natural background radiation. The risk of any side effects from this level of exposure is minimal.

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. Male or female subjects 25 to 80 years of age
2. Documented diagnosis of knee OA (osteoarthritis or post-traumatic osteoarthritis), which includes clinical symptoms of medial compartment osteoarthritis (pain primarily localized to the medial aspect of the knee and generally exacerbated by weight bearing)
3. Radiographic confirmation of mild to moderate medial compartment knee OA as demonstrated by a Kellgren-Lawrence grade of 1, 2 or 3 (scale 0-4) as assessed by the Investigator
4. Has failed at least six months of conservative treatment prior to surgery with continued OA pain. Prior conservative therapy is defined as treatment including at least one of the following:
a. Lifestyle modification
b. Weight loss, if BMI >25
c. Pain relievers
d. IA corticosteroid injections
5. Knee flexion range >=90 - <=150 degrees
6. WOMAC pain score of at least 40 (scale 0-100) at the baseline visit
7. BMI < 35 or weight < 300 lbs
8. Candidate for a high tibial osteotomy procedure
9. Subjects who are able to give voluntary, written informed consent to participate in this clinical investigation and from whom consent has been obtained
10. Subjects, who, in the opinion of the Clinical Investigator, are able to understand this clinical investigation, cooperate with the investigational procedures and are willing to return for all the required post-treatment follow-ups.

Exclusion criteria

1. Symptomatic OA in lateral or patellofemoral compartment of affected knee, i.e. clinical

symptoms or radiographic evidence of advanced OA in lateral or patellofemoral compartment of the affected knee
2. Symptomatic OA with Kellgren Lawrence Grade 4 in the contralateral knee likely to necessitate surgical intervention within 12 months of enrollment, i.e. contralateral knee has radiographic evidence of severe OA (Kellgren Lawrence Grade 4), clinical findings of severe OA (severe joint pain or limitation of movement) or symptoms that interfere with activities of daily living, stair climbing, stair descending or requires the use of an assist device
3. Tibial-femoral varus or valgus alignment >10 degrees (assessed by the investigator)
4. Flexion deformity > 10 degrees
5. Hyperextension >5 degrees
6. Severe deformities leading to impaired fixation or improper positioning of the implant
7. Pathologic ligamentous instability (>1 MCL injury or Lachman >1) as assessed by the Investigator on physical examination
8. Neuropathic pain or fibromyalgia, or any knee or other pain requiring chronic pain management.
9. Active infection, sepsis or osteomyelitis, history of infection in the target knee or distant foci of infections which may spread to the implant site
10. Previous joint modifying surgery in the target knee are excluded within 12 months prior to planned study surgery date, such as ligament reconstruction or meniscus repair, cartilage transplantation, and microfracture. Arthroscopic surgeries for joint lavage, menisectomy, chondral debridement, and loose body removal are excluded within 3 months prior to planned study surgery date.
11. Previous osteotomy or failed knee joint replacement in the target knee
12. Known sensitivity to metal implants
13. Rheumatoid arthritis, other forms of inflammatory joint disease or autoimmune disorder
14. Paget*s disease or metabolic disorders which may impair bone formation
15. Moderate to severe osteoporosis or pathologic fractures as evidenced by radiolucency of the femoral or tibial cortex on x-ray
16. Charcot*s joint disease or other severe neurosensory deficits
17. Immunologically suppressed or immunocompromised
18. History of systemic steroid treatment, medication use that affects bone metabolism (such as chemotherapy) within the previous 6 months, or radiotherapy within the previous 6 months
19. Any significant medical condition (e.g., diabetes mellitus requiring daily insulin therapy, advanced liver disease, advanced kidney disease, congestive cardiac failure, uncontrolled transient ischemic attack, cancer, radicular symptoms associated with lumbar spine pathology); significant psychiatric disorders (such as major depression, anxiety disorders, bipolar disorders and schizophrenia), history of or active alcohol/drug abuse (meeting standard diagnostic criteria described in the Diagnostic and Statistical manual for Mental Disorders DSM-IV); or other factors (e.g. planned relocation, uncooperative patient)
20. Under litigation or workers compensation for musculoskeletal injuries or disorders
21. Is either pregnant or interested in becoming pregnant during the duration of the study
22. Subjects who are currently involved in any investigational drug or device trial or have been enrolled in such trials within the last 3 months.
23. Prisoners or wards of the state.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-04-2014
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	KineSpring®
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	31-01-2014
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	25-02-2015
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	15-12-2015
Application type:	Amendment

Review commission: METC Noord-Holland (Alkmaar)

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
ClinicalTrials.gov	NCT01610505
CCMO	NL38105.094.13

Study results

Results posted: 06-08-2020

First publication
02-07-2020