Agili-C Implant Performance Evaluation in the Repair of Cartilage and OCD

Published: 22-09-2014
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Evaluate the performance of the Agili-C in the repair of Cartilage and Osteochondral defects.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON41021

Source
ToetsingOnline

Brief title
Agili-C trial

Condition

- Joint disorders

Synonym
articular cartilage lesion; articular cartilage defect;

Research involving
Human

Sponsors and support

Primary sponsor: Cartihael (2009) Ltd.
Source(s) of monetary or material Support: de opdrachtgever Cartihael (2009) Ltd.

Intervention

Keyword: Cartilage defect, Osteochondritis Dissecans

Outcome measures

Primary outcome

Improvement in KOOS Pain Subscale

Secondary outcome

• Improvement in KOOS Score and Subscales

• Improvement in IKDC Subjective Knee Score (and VAS as part of it)

• Improvement in Knee Examination Form - 2000

• Improvement in SF 36 Questionnaire

• Improvement in Tegner score

• Improvement in Lysholm Knee Coring Scale

• Improvement in new MOCART Scoring

Study description

Background summary

The natural joint consists of two main tissues: articular cartilage and subchondral bone. Together they form the load-bearing system that allows the normal large joint range of motion. The cartilage protects the subchondral bone from high stresses, absorbs shock, distributes load, facilitates stable motion within the joint and provides the self-lubricating surface. Unlike other tissues, cartilage is generally considered to have a very limited capacity for self-repair. Defects and degeneration of the articular cartilage surfaces of joints cause pain, joint swelling and stiffness; moreover, they can lead to premature joint degradation (meaning decrease in function and joint motion). Damage to the cartilage might be a result of a wide variety sources such as physical injury, trauma, sports, disease and repetitive stresses.

Current treatments for cartilage damage, such as debridement or micro fracture, often generate scar tissue (Fibrocartilage) and no hyaline cartilage. This tissue does not have sufficient inferior biomechanical properties to bear weight.

Agili-C is a natural, single-step implant that allows a full regeneration of

hyaline cartilage, which previously was not possible, and leads to an optimal recovery of cartilagelesions.

Study objective

Evaluate the performance of the Agili-C in the repair of Cartilage and Osteochondral defects.

Study design

Prospective, Interventional, Non-Randomized, Open Label, Single Group Assignment, Multi Center, Multi national study .

Intervention

Each study participant will receive the Agili-C bi-phasic Implant: this trial is single-arm, meaning that all the patients enrolled in the trial will undergo the implantation of the device.
The implantation is performed during an arthroscopy or mini-arthrotomy procedure and requires general anaesthesia, as per surgeon*s discretion. The surgeon will remove the diseased area of cartilage and bone and insert a cylindrical Agili C implant to replace this area. This insertion might require opening the joint through a larger incision (mini-arthrotomy) or through the same mini-puncture wounds of the arthroscopy itself. This depends on the location of the damaged area as well as its extent and other factors, and will be decided by your surgeon during surgery.
In case more than one indication will be treated (e.g. reconstruction of ligaments), there is a possibility that a larger incision or other associated procedures will be required during the surgery, depending on findings during the procedure.

Study burden and risks

The burden for the trial participants is that they have to undergo a more extensive post operative follow up and rehabilitation program compared to standard patients treated outside this study.

The possible risks of this study are risks associated in general in kneesurgeries, risks related to the device and additional risks. (see E9).

The subjects treated with Agilig-C may benefit, compared to standard microfracture, from a better reduction of pain and an improved clinical outcome.

Contacts

Public
Cartihael (2009) Ltd.

Atir Yeda 17
Kfar Saba 4464313
IL
Scientific
Cartihael (2009) Ltd.

Atir Yeda 17
Kfar Saba 4464313
IL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. 18 to 55 years
2. Symptomatic, Painful, single, focal, full or near full-thickness (ICRS cartilage defect description grades 3 and 4) chondral or osteochondral (grade 1,2,3,4A) isolated lesion of the femoral condyle, trochlea or the tibial plateau (limited to 4 millimeters in depth).
3. KOOS pain score is < 60 at baseline evaluation
4. Defect area is less than 3.5 cm^2. The defect is completely surrounded on all sides by healthy cartilage.
5. Primary or secondary articular cartilage repair.
6. Knee is stable or can be stabilized as a concomitant procedure.
7. Must be physically and mentally willing and able to comply with post-operative rehabilitation and routinely schedule clinical and radiographic visits.
8. Informed consent signing.

9. Any misalignments must be fully corrected at the end of the operative procedure.

Exclusion criteria

1. Uncorrected axial misalignments >5° that cannot be corrected.
2. Patellar cartilage defects or pathology.
3. Meniscal resection of more than 50%, either in a previous procedure or concomitant with articular cartilage repair.
4. Any tumor of the ipsilateral knee, any concurrent malignant tumor or any metastatic tumor in the past or in the present.
5. Present or past acute or chronic infection of the treated knee.
6. Inflammatory arthropathy or crystal-deposition arthropathy.
7. Systemic cartilage and/or bone disorder; This implant's integration is dependent on surrounding live bleeding bone; therefore it must not be implanted within sequestrated or necrotic bone
8. Bony defect depth over 4 millimeters.
9. Body mass index >35.
10. Asymptomatic articular cartilage defects.
11. Bipolar articular cartilage defects.
12. Osteoarthritis of the operated knee.
13. Oral medications such as systemic corticosteroid therapy taken less than one year prior to the surgery or chemotherapy.
14. Previous arthroscopic marrow stimulation or cell therapy within the last 6 months
15. Any previous cartilage treatment within the last 6 months
16. Patients who are sensitive to materials containing calcium carbonate or hyaluronate.
17. Pregnant women, Women of Childbearing Potential [WOCBP-defined as any female who has experienced menarche and does not meet the criteria for *Women Not of Childbearing Potential* which are: women who are postmenopausal,permanently sterilised (e.g. tubal ligation, hysterectomy, bilateral salpingectomy)], women who are not using a highly effective contraception method (as defined by ICH M3) during the entire duration of the clinical trial or breastfeeding women.
18. Evidence of any significant systemic disease (such as but not limited to HIV infection, hepatitis infection or HTLV infection), known coagulopathies, severe vascular or neurological disease or acute injury that might compromise the Subject's welfare.
19. Substance abuse or alcohol abuse.
20. Participation in other clinical trials in parallel to this study.
21. Type I diabetes.
22. Unable to undergo MRI or X-ray.
23. Any reasons making the Subject a poor candidate in the opinion of the investigator.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Agili-C Implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-09-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL49634.018.14