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

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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-OMON42688

Source
ToetsingOnline

Brief title
Agili-C AMC trial

Condition

- Joint disorders

Synonym
articular cartilage lesion; articular cartilage defect;

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cartilage defect, Osteochondritis Dissecans

Outcome measures

Primary outcome

The KOOS Pain Subscale relative to baseline [time frame: 6, 12,18 and 24 months

Secondary outcome

* Improvement in IKDC Subjective Knee Score relative to baseline [time frame:

6, 12,18 and 24 months]

* Joint Space maintenance rate according to X-ray [time frame: 12 and 24 months]

* Improvement in other KOOS subscales relative to baseline [time frame: 6,

12,18 and 24 months]

* Improvement SF -36 Survey [time frame: 6, 12,18 and 24 months]

* Improvement in Tegner score [time frame: 6, 12,18 and 24 months]

* Improvement in Lysholm Score [time frame: 6, 12,18 and 24 months]

* Defect Fill according to MRI [time frame: 6, 12, 18 and 24 months]D

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 cartilage lesions.

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, 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

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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. 18 years or older
2. Cartilage lesion of the operated knee graded up to grade III according to the Kelgren-Lawrence scale with known ICRS IIIa * IVb lesion (s) on the femoral condyles or the trochlea, not eligible for microfracture and who failed conservative treatment
3. The total area of the treated lesions is up to 6 cm2
4. KOOS pain score at baseline is not less than 30 and not more than 65
5. Must be physically and mentally willing and able to comply with post-operative rehabilitation and routinely scheduled clinical and radiographic visits.

6. Informed consent signing

Exclusion criteria

1. Untreated ACL and/or PCL, ACL and/or PCL deficiency or ligamentous instability in involved knee
2. Misalignments larger than 5° from neutral that are not correctable
3. Any known tumor of the ipsilateral knee
4. Any history of infection of the treated knee
5. Inflammatory arthropathy or crystal-deposition arthropathy
6. Tobacco user
7. Systemic cartilage and/or bone disorder e.g. but not limited to chondrodysplasia or osteogenesis imperfecta
8. Body mass index >35
9. Osteoarthritis of the operated knee graded as 4 according to the Kelgren-Lawrence scale
10. Chemotherapy treatment in the past 12 months
11. Any previous surgical cartilage treatment within the last 6 months
12. History of allergic reaction or intolerance of materials containing calcium carbonate or hyaluronate
13. Patient who is pregnant or intends to become pregnant during the year following initial enrollment
14. History of any significant systemic disease, such as but not limited to, HIV infection, hepatitis infection or HTLV
infection; known coagulopathies, that might compromise the Subject's welfare
15. Known Substance abuse or alcohol abuse
16. Participation in other clinical trials in parallel to this study
17. Known insulin dependent diabetes mellitus
18. Unable to undergo MRI or X-ray

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:	12-04-2016
Application type:	First submission
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	NL55085.018.15