Evaluation of an Acellular Osteochondral Graft for Cartilage LEsions European Post Market Study

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The purpose of this study is to confirm the safety and performance of the BioMatrix CRD for the repair of focal articular cartilage lesions or osteochondral defects in the knee.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON41787

Source
ToetsingOnline

Brief title
The EAGLE European Post Market Study

Condition

- Tendon, ligament and cartilage disorders

Synonym
articular cartilage lesion, osteochondral defect

Research involving
Human

Sponsors and support

Primary sponsor: DSM Biomedical
Source(s) of monetary or material Support: DSM Biomedical

Intervention

Keyword: cartilage, medical device, post-market study, repair

Outcome measures

Primary outcome

The primary endpoint is the rate of implant failure resulting in device removal

and/or further surgical intervention due to a device related complication

through 24 months post operative.

Secondary outcome

Secondary Safety Endpoints:

1. Rate of reparative tissue hypertrophy

2. Rate of implant migration

3. Rate of infection in the area of the implant

4. Rate of individual adverse events attributable to the BioMatrix CRD implant

5. Rate of serious adverse events associated with the surgical procedure

Secondary Performance Endpoints:

1. Rate of > 50% cartilage defect filling as assessed on the 24 month MRI scans.

2. Rate of improvement in treated joint pain as measured on a KOOS Pain

Subscale at each post-operative visit

3. Rate of improvement in the IKDC score at each post-operative visit

4. Rate of complete borderzone integration as assessed on the 24 month MRI

scans

Study description

Background summary

Damage to articular cartilage in the knee by acute or chronic injury causes pain and limits knee function. If left untreated, damage to the articular cartilage can lead to painful osteoarthritis. The human body has a limited ability to regenerate or adequately repair damage to articular cartilage. Over the past twenty years, several surgical techniques have been developed to assist the repair of articular cartilage and improve pain and function. Microfracture, currently the most commonly used technique for cartilage repair, involves the creation of numerous small fractures in the subchondral bone with an awl. These small fractures cause the release of multipotential stem cells from the bone marrow creating a clot on the surface. Over time, this clot causes reparative fibrocartilage to form. However, fibrocartilage is less durable and lacks the mechanical properties of normal articular cartilage. Success rates reported in the literature for microfracture range from 50 - 80%. Beyond 2 years after the initial microfracture, functional deterioration is seen in 47 - 80% of patients. Success is dependent on the patient*s compliance with a comprehensive rehabilitation program.
Like the BioMatrix CRD, TruFit is a resorbable, biphasic implant consisting of a mineral ceramic suspended within a polymer matrix. In 2005, the TruFit implant received the CE Mark. TruFit consists of polylactic acid/polyglycolic acid co-polymer and calcium sulfate mineral. In both devices, the polymer is used to provide a porous matrix, which allows tissue ingrowth and exposure to the mineral ceramic. Both devices are provided in cylinder shape in varied diameters and are packaged within a similar delivery device.
In several studies of the use of CB-TruFit plugs has been shown as safe and performant in the recovery of damage to articular cartilage.

DSM Biomedical showed based on numerous animal studies, a literature review of the TruFit * CB-plug and a retrospective clinical study in humans, the safety and performance of themedical device. The British Standards Institution ("BSI", British Standards Institute') granted a CE Mark certificate in February 2010 .
As a prerequisite for the CE marking BSI demanded that DSM Biomedical would perform a clinical post-market study to confirm the safety and performance of the medical device.

Study objective

The purpose of this study is to confirm the safety and performance of the BioMatrix CRD for the repair of focal articular cartilage lesions or osteochondral defects in the knee.

Study design

Prospective, multi-center, non-randomized, historical controlled study of 50 patients requiring surgical repair of a focal articular cartilage lesion or

osteochondral defect in the knee.

Intervention

Implant of the BioMatrix

Study burden and risks

The potential complications associated with the BioMatrix CRD and the rates of occurrence are expected to be similar to those associated with the other knee cartilage repair techniques. The potential complications associated with cartilage repair techniques include:
• Infection in the bone, bone marrow or joint space
• Bone cyst formation
• Bony overgrowth
• Local or systemic allergic reaction to the materials in the BioMatrix CRD
• Fluid in the joint
• Knee swelling
• Knee pain and/or stiffness
• Joint inflammation
• Cartilage repair tissue complications such as movement or breakage
• Cartilage repair tissue overgrowth
• Injury to the surrounding cartilage

Women who are pregnant cannot take part in this study. This is applicable for the first 12 months of the study.

There is no guarantee that the subject will benefit from participating in the study. The majority of patients undergoing cartilage repair procedures experience decreased knee pain and increased knee function following the procedure and rehabilitation. However, repair tissue created following microfracture (the most common cartilage repair technique) consists mainly of a sub-optimal tissue known as fibrocartilage and functional deterioration is seen in a majority of patients beyond 2 years post-operative. The majority of patients treated with the BioMatrix CRD also experience decreased knee pain and increased knee function. Over time, cartilage tissue and bone grow into the BioMatrix CRD. Compared to microfracture, the repair tissue in BioMatrix CRD resembles normal cartilage, which is more durable than the fibrocartilage produced by the microfracture.
It is thanks to this type of research better treatments for torn anterior cruciate ligament cartilage repair can be developed.

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. The patient is * 18 years old and skeletally mature (i.e. closed epiphyses).
2. The patient is male or a non-pregnant female who does not intend to become pregnant during the next 12 months.
3. The patient has a pre-procedure KOOS Pain subscale score is * 70.
4. The patient has an ICRS grade 3 or 4 focal articular cartilage lesion on the medial femoral condyle, lateral femoral condyle or trochlea, which measures 15mm in diameter. Note: only one knee per patient may be treated with BioMatrix CRD.
5. The cartilage lesion is amenable to treatment with a single BioMatrix CRD or an osteochondral autograft. Note: when an osteochondral autograft is harvested to repair the cartilage lesion, the harvest site defect is to be filled with BioMatrix CRD.
6. The patient has >= 50% of the meniscus remaining bilaterally with a stable rim.
7. The patient has the mental capacity and the willingness to comply with the post-operative

rehabilitation plan, specified follow-up evaluations and can be contacted by telephone by site personnel.
8. The patient is willing and able to sign the informed consent document.

Exclusion criteria

1. The patient is contraindicated for MRI (i.e. pacemaker, defibrillator, cochlear
2. The patient has had a previous cartilage repair procedure (i.e., microfracture, OATS, ACI) at the intended BioMatrix CRD implantation site. Note: patients having prior debridement only at the intended BioMatrix CRD implantation site are eligible.
3. The patient had surgery in the injured knee within the last 6 months.
4. The patient has clinically significant (> 5 degrees) varus or valgus malalignment in either knee. Note: concurrent osteotomy is permissible.
5. The patient has >= grade 2 joint space narrowing on the Kellgren-Lawrence scale.
6. The patient has documented history or peri-operative diagnosis of osteoarthritis in the injured knee.
7. The patient has inflammatory arthropathy (i.e., rheumatoid arthritis, systemic lupus or active gout) or any synovial proliferative disorder. Note: patients noted to have pseudogout are eligible.
8. The patient has osteomyelitis or other active infection in either lower limb.
9. The patient has had cortisone or hyaluronic acid knee injections in the past 3 months
10. The patient has a body mass index greater than 35.
11. The patient has a history of substance abuse (e.g., recreational drugs, narcotics, or alcohol).
12. The patient was diagnosed with cancer within the last 2 years and received treatment with chemotherapy or received radiation therapy to the injured lower extremity.
13. The patient has a known allergy to the materials in the BioMatrix CRD.
14. The patient is currently involved in a study of an investigational product for a similar purpose.
15. The patient has a known co-morbidity that reduces life expectancy to less than 24 months.

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):	01-10-2015
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	BioMatrix CRD
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-04-2015
Application type:	First submission
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
ClinicalTrials.gov	NCT02309957
CCMO	NL50131.068.14