The effect of coblation treatment on knee cartilage quality in patients with meniscal lesions and cartilage loosening of the knee

Published: 21-01-2019
Last updated: 12-04-2024

Primary Objective: To study the in vivo effect of coblation treatment on knee cartilage quality in patients with meniscal lesions and partial cartilage loosening of the knee.Secondary Objective: To study the relationship between knee cartilage...

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

Summary

ID

NL-OMON52659

Source
ToetsingOnline

Brief title
Coblation study

Condition

- Tendon, ligament and cartilage disorders

Synonym
meniscal injury and cartilage loosening

Research involving
Human

Sponsors and support

Primary sponsor: Rijnland Ziekenhuis

Source(s) of monetary or material Support: Alrijne Ziekenhuis

Intervention

Keyword: cartilage quality, coblation, knee, Na18F-PET/CT

Outcome measures

Primary outcome

The Outerbridge cartilage lesion grading score at one-year follow-up of the treatment region.

Secondary outcome

• The quantifiable Na18F-PET/CT tracer uptake in Standardized Uptake Values (SUV) and target to background ratio (TBR). (Jonnakuti et al. 2018)

• Patient reported outcome of knee function, quality of life and pain will be collected preoperatively, and at 3, 6 and 12 months

• Cartilage thickness in mm of the treatment region

Study description

Background summary

Healthy cartilage of the knee joint with smooth articular surfaces is important for normal physiological knee function. Cartilage defects of the knee are quite common, affecting about 10% of the population. (Sellards, 2002) Cartilage lesions are detected in approximately 60% of all knee arthroscopies (Widuchowski, 2007). Small cartilage lesions are usually not treated surgically, whereas larger defects or unstable cartilage flaps are treated with different surgical procedures, ranging from lavage, bone marrow stimulation, tissue transplantation or mechanical debridement (MD).

Coblation treatment of degenerative cartilage in the knee is a safe alternative to MD. With coblation treatment, radiofrequency energy is used to break molecular bonds to dissolve soft tissue at low relative temperatures. Recent studies have shown that coblation treatment creates a smoother cartilage surface in human cadavers compared to MD (Gambardella, 2016), and this effect

is maintained up till 6 months in goat model studies. (Smith & Nephew) Human in vivo studies have shown that coblation treatment results in better patient reported outcome up till 10 years when compared to mechanical debridement. (Spahn 2008, 2010, 2016). Second-look arthroscopy at different follow-up moments showed that 3 out of 25 patients treated with coblation therapy demonstrated evidence of progression. (Voloshin, 2007). However this was studied in a small part of a larger cohort and at varying follow-up.

PET/CT is a nuclear imaging technique with the ability to fuse functional and anatomical imaging. PET/CT using Na18F (Na18F-PET/CT) enables the identification of increased bone turnover and provides 3D-quantitative data on osteoblastic activity. Although it is mainly used for oncological indications, the use for benign bone and joint disorders, including the knee, is a novel application of Na18F-PET/CT. (Smit 2017; Jonnakuti et al. 2018; Haddock et al. 2019; van der Bruggen et al. 2020) Arthrography, using intra-articularly injected contrast agent, is an established clinical technique for imaging of cartilage abnormalities (Omoumi et al. 2009, 2017)(Omoumi et al. 2009 en 2017). The combination of nuclear imaging and arthrography provides functional information about increased bone turnover with morphological details of knee. (Bhure U, Roos JE, Pérez Lago MDS, Steurer I, Grünig H, Hug U 2018) Therefore, Na18F-PET/CT with arthrography of the knee is a promising tool for non-invasive assessment of cartilage. (Smit 2017; Bhure U, Roos JE, Pérez Lago MDS, Steurer I, Grünig H, Hug U 2018; Jonnakuti et al. 2018) The in vivo effects of coblation treatment on knee cartilage in a larger patient cohort up to one year post-treatment have not been studied. Na18F-PET/CT with arthrography can be used to study these effects.

Study objective

Primary Objective:
To study the in vivo effect of coblation treatment on knee cartilage quality in patients with meniscal lesions and partial cartilage loosening of the knee.

Secondary Objective:
To study the relationship between knee cartilage quality after coblation treatment, and patient reported outcome and patient characteristics.

Study design

A cohort study, with follow-up up till one year after surgery.

Intervention

Radiofrequency energy is applied using the Werewolf Coblation system (Smith & Nephew Inc., Cordova, TN, USA). The WEREWOLF System and FLOW 50 Wand using Lo mode is FDA-cleared for chondroplasty and articular cartilage debridement. This

low-energy, low-suction setting minimizes damage to surrounding healthy chondrocytes and is therefore the preferred setting for articular cartilage removal. A traditional two-portal (anterolateral and anteromedial) arthroscopy will used to perform the chondroplasty treatment. (Gambardella, KNEE TECHNIQUE GUIDE)

Study burden and risks

The benefits for the subjects are that, according to the current literature, coblation treatment results in better patient reported outcome when up to 10 years when compared to mechanical debridement. The extra time subjects have to invest in the study is about 4.5 hours over a year, with one extra visit to the hospital. This may be beneficial for some subjects, with an extra long-term check-up. There is a low risk of infection, and skin irritation due to leakage after intravenous injection of the tracer. Otherwise, both coblation treatment and Na18F-PET/CT are safe procedures and the burden of the PROMS are low. Average radiation dose for Na18F-PET/CT is 1.96 mSv, resulting in 2 x 1.96 mSv = 3.92 mSv over the course of a year. This falls in the risk classification 3: 1-10 mSv and is considered safe since this is less than two times the annual natural background radiation in the Netherlands (2.5 mSv/year).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- focal cartilage lesions, ICRS grade 2-3a (i.e. partial thickness)
- meniscal laesions
- age between 18y and 65y

Exclusion criteria

- Subjects who do not understand Dutch written language, necessary for completing the PROMS
- Systemic or autoimmune disease (e.g. RA)
- Clinical signs of polyathrosis
- Posttraumatic functional disabilities

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2021
Enrollment:	25
Type:	Anticipated

Medical products/devices used

Generic name:	Werewolf Coblation system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-01-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	20-05-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-05-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL66214.058.18