Protocol CE-marking steerable punch - A case series study on safety, efficiency, and quality of the steerable punch for future CE-marking

Published: 22-11-2018
Last updated: 10-04-2024

The main objective of this study is to assess the safety, efficiency, and quality of the steerable punch for future CE-marking

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

Summary

ID

NL-OMON46381

Source
ToetsingOnline

Brief title
Steerable punch

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Meniscal rupture, Meniscal tear

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Knee surgery, Meniscal trauma, Meniscus rupture, Steerable punch

Outcome measures

Primary outcome

The main study parameter is safety, expressed by the instrument intactness during ten cycles of cleaning, sterilisation and use during a meniscectomy procedure. That is no failure will occur in terms of breakage or bending of parts or rejection in the cleaning process [dichotomous score: yes/no]. We will use three prototypes, one per surgeon. The endpoint for each surgeon is failure of the steerable punch before ten cycles or upon completion of ten cycles.

Secondary outcome

1. Assessment of quality measured by scoring the quality of the remaining rim by two independent experts using a still of an arthroscopic image after completion of the meniscectomy showing the full part of the rim that has been treated. Scoring is performed based on the IKDC form meniscus section[17]. Additionally results will be scored Scores the result based on a classification of the IKDCI-IV

a. I. Fully smooth and stable meniscal rim

b. II. Somewhat rough edges but acceptable

c. III. Rough edges, requires refinement

d. IV. Failed surgery, needs to be done over

2. Assessment of usability:

A. Documentation of the number of errors made by the surgeon (surgical actions)

and the scrub nurse ((dis)assembly) when handling the steerable punch based on video recordings with two video cameras in operating room.

B. (Dis)assembly time of the steerable punch performed by the scrub nurse in the operating room determined from video footage

C. Questionnaire filled out by the surgeon assessing the workload[18] and ergonomic comfort (see attachment F1).

D. Questionnaire filled out by the scrub nurse assessing the workload and ergonomic comfort (see attachment F1).

E. Questionnaire filled out by the personnel of the sterilization department assessing workload and ergonomic comfort (see attachment F1).

3. Assessment of patient recovery using the IKDC (see attachment F1)

4. Assessment of postoperative complications including postoperative infection assessed at the regular follow-up two and 6 weeks postoperatively using Patient Reported Outcome Measures (PROMs) which are filled out with CASTOR as part of standard follow up of our patients.

5. Assessment of efficiency measured by:

A. Time to perform solely the cutting of the meniscus, which is derived from video recording of the arthroscopic images during the operation.

B. Number of repetitive actions during solely the cutting of the meniscus, i.e. repetitive reorientation of steerable punch, repetitive grasping of meniscal tissue before cutting, reinsertion of steerable punch, repetitive adjusting grip without performing a goal-oriented action

Study description

Background summary

The menisci are responsible for resorbing 50-70% of the load across the knee compartment. The most common cause of meniscal injury are traumatic injuries in younger adults and degeneration in older adults. When the meniscus is torn, the loading in the knee is disturbed resulting in complaints such as pain, swelling and clicking. In a minimally invasive surgical procedure (meniscectomy), the torn part is cut with a slender rigid cutting instruments (punches). The rigidity in combination with the tightness and curvature of the knee joint gives limitations in reaching the tear, optimal surgical workflow and quality of the cut. The newly developed steerable punch having a sideways steerable instrument tip solves these limitations. To allow market entry of this surgical instrument ,evidence needs to be collected showing its compliance with the medical devices safety regulations.

Study objective

The main objective of this study is to assess the safety, efficiency, and quality of the steerable punch for future CE-marking

Study design

Case series

Intervention

Routine meniscectomy procedure with the steerable punch instead of ordinary punches.

Study burden and risks

The benefit for the patients can be a shorter operation time, thus a shorter period of anaesthetics, less risk on overloading of the access portals or cartilage and a more smooth stable meniscal rim that enhances recovery. Finally, the surgical workflow is optimized which induces less risk of unintended damage.
The main potential risk (a full risk analysis can be found in the IMDD) is peroperative breakage of a part of the tip of the steerable punch. In a previous submitted cadaver study, breakage of these parts did not occur [18]. In this 0-series prototype, utmost care is taken to even further strengthen the weakest parts and prevent this. Furthermore, the steerable punch is designed such that if the weakest parts break, the broken part is sized such that it can be grasped and taken out the knee joint. Subsequently, the surgical procedure

can be continued with normal punches. Therefore, we assume the risk is minimal for the patient, but with the benefit of receiving a high quality and efficient surgical procedure.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- 16 years or older;
- diagnosed with a traumatic meniscal tear;
- scheduled for an operation to cut the traumatic meniscal tear.

Exclusion criteria

- Systemic disease;
- Previous meniscal/knee operations;
- Degenerative meniscal tear or osteochondritis dissecans
- No laxity of the knee (anterior/posterior drawer test of no more than 6 mm and negative Lachman test)
- Pregnant

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	22-11-2018
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	NL63171.018.18