Needle arthroscopic meniscopexy

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20688

Source
NTR

Brief title
TBA

Health condition

Peripheral tear in the red-red or red-white zones of the medial or lateral meniscus

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Arthrex GmbH

Intervention

Outcome measures

Primary outcome

Hospital Anxiety and Depression Scale (HADS), pre-operatively, at discharge and at 1-day follow-up

Secondary outcome

General
- Serious adverse events (results in death, is life-threatening at the time of the event,

requires
hospitalization, results in persistent disability or incapacity)
- Adverse events (infection, bleeding requiring re-operation, neurological damage present at 3-month followup)
- Failure of the needle arthroscopic procedure due to e.g. need for general or regional anesthesia (e.g. due to an intolerable procedure under local anesthesia), device failure, inability to perform an adequate meniscopexy, inaccessibility of the joint
- Procedure time
- Hospital length of stay

Functional outcome
- Range of motion of the joint
- Presence of residual complaints requiring additional surgery (yes/no)

Patient reported outcome
- Hospital Anxiety and Depression Scale (HADS)
- NRS of pain, measured a. at rest and b. after mobilization
- Ability to walk normally
- Ability to perform professional work
- KOOS
- EQ5D
- NRS of satisfaction
- Net Promoter Score (NPS)
- Use of opioids
- Use of home care support

Costs

Study description

Background summary

The overall aim of this study is to evaluate the use of needle arthroscopy for in-office treatment of meniscal tears with meniscopexy under local anesthesia. This treatment entails repair of the tear with sutures and may include limited debridement if necessary. The primary study objective is to evaluate patient experience compared to traditional arthroscopic meniscopexy. As secondary objectives this study will compare meniscopexy using in-office needle arthroscopy and traditional in-OR conventional arthroscopy in terms of time-to-recovery, functional outcome and overall costs. We hypothesize that compared to in-OR surgical intervention, in-office treatment will be preferred by patients, decrease time-to-recovery and be less costly.

Study objective

We hypothesize that compared to traditional in-OR surgical intervention, in-office, needle arthroscopic meniscopexy will be preferred by patients, decrease time-to-recovery and be less costly.

Study design

- Baseline
- Pre-op
- Discharge
- +1 day post-op
- +2 days post-op
- +7 days post-op
- +3 months post-op

Intervention

There are two intervention groups. In each group, an arthroscopic meniscopexy is performed. In
- Group 1, mensicopexy is performed with traditional arthroscopy, in the operating theatre, using general or regional anesthesia
- Group 2, meniscopexy is performed with needle arthroscopy, in the office procedure room, using local anesthesia

Contacts

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Eligibility criteria

Inclusion criteria

Adult patients who are planned for meniscopexy on account of a peripheral tear in the red-

red or red-white zones of the medial or lateral meniscus, and who provide informed consent for study participation.

Exclusion criteria

- Patients who were unable to mobilize independently prior to their meniscal injury
- Findings during diagnostic work-up in support of concomitant traumatic pathology that may hamper postoperative mobilization, as e.g. substantial damage to the cruciate ligaments
- Excessive difficulty in performing an in-office meniscopexyas expected by the treating surgeon
- Patients who do not agree to participate in the study's follow-up activities
- Recent (< 1 year) history of diabetes, myocardial infarction, congestive heart failure, stroke, thromboembolic events, respiratory disease, opiate use, depression or anxiety disorder
- Adiposity grade I (BMI > 30 kg/m2)
- ASA ≥ 3
- Unable to provide informed consent
- A known history of coagulopathy
- Use of anticoagulation medication, other than a single thrombocyte aggregation inhibitor

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	22
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	26-08-2020
Application type:	First submission

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
NTR-new	NL8860
Other	METC AMC : W20_357 # 20.412

Study results