Needle arthroscopic meniscopexy

Gepubliceerd: 26-08-2020 Laatst bijgewerkt: 13-12-2022

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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20688

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

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

Ondersteuning

Primaire sponsor: Amsterdam UMC
Overige ondersteuning: Arthrex GmbH

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	22
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	26-08-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8860
Ander register	METC AMC : W20_357 # 20.412

Resultaten