Capsular closure versus unrepaired capsulotomy in hip arthroscopy

No registrations found.

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

Summary

ID

NL-OMON22309

Source
NTR

Brief title
CLOSE

Health condition

Femoracetabular impingement.
Hip arthritis
Hip arthroscopy.

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none declared

Intervention

Outcome measures

Primary outcome

NRS painscore system measured the first 12 weeks postopearatively

Secondary outcome

HAGOS, iHOT 33 and Tegner activity scale are functional outcome scores.

These scores will be our secondary outcomes at 52 weeks follow up after surgery.

Study description

Background summary

Hip arthroscopy is a becoming more and more popular procedure for hip pathology. So far it is unknown what the influence is of routine capsular closure after a procedure.
This trial randomizes patients between capsular closure and unrepaired capsulotomy after hip arthroscopy.

Primary outcome is pain measured with the NRS the first 12 weeks after surgery.

Secondary outcome are functional outcome scores at 2,6,12 and 52 weeks after surgery.

Study objective

Primary hypothesis: Capsular repair results in less postoperative pain 12 weeks after surgery compared to capsulotomy in patients undergoing hip arthroscopy.

Secondary hypotheses:
Capsular repair results in less postoperative pain at
all other time points (1 to 12 weeks, and
52 weeks postoperatively) after surgery compared to capsulotomy in patients undergoing hip arthroscopy.

Capsular repair results in better Patient Reported Fu
nctional Outcome Scores after surgery
compared to capsulotomy in patients undergoing hip arthroscopy.

Study design

NRS pain score the first 12 weeks weekly

Functional outcome scores measured at 2,6,12 and 52 weeks postoperatively

Intervention

Hip capsular closure versus unrepaired capsulotomy

Contacts

Public
MC Slotervaart
Louwesweg 6
Niels. H. Bech
Amsterdam 1066 EC
The Netherlands
06-30563088
Scientific
MC Slotervaart
Louwesweg 6
Niels. H. Bech
Amsterdam 1066 EC
The Netherlands
06-30563088

Eligibility criteria

Inclusion criteria

Age between 18-65 years

Weight BMI < 35

Signed infomed consent

Intra-articular hip pathology suitable for hip arthroscopic surgery

Good understanding of Dutch/English language

Exclusion criteria

Revision hip arthroscopy

Extra-articulair hip pathology

Documented systemic connective tissue disease

Prior hip surgery

Prior hip disease or fracture

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2016
Enrollment:	116
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-06-2016
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	NL5749
NTR-old	NTR5903
Other	: P1562

Study results