

Long term follow up after Pyrocarbon disc interposition for thumb CMC osteoarthritis

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Retrospective evaluation of the long term results after treatment of thumb base osteoarthritis with a pyrocarbon disc. We want to enroll this study in the Jeroen Bosch Ziekenhuis in 's Hertogenbosch and in the University Medical Center in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON45594

Source

ToetsingOnline

Brief title

Long term follow up after pyrocarbon disc interposition for CMC1 OA

Condition

- Bone and joint therapeutic procedures

Synonym

CMC 1 OA, thumb base osteoarthritis

Research involving

Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis

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

Intervention

Keyword: Carpometacarpal (CMC), osteoarthritis, pyrocarbon disc interposition, treatment

Outcome measures

Primary outcome

We hypothesize that, compared to other techniques in literature, pyrocarbon interposition results in:

1. Good functional recovery compared with the thumb function before surgery, with return to previous work
2. Less pain compared to the pain before surgery
3. High patient satisfaction after treatment
4. Less post-operative complications than other interposition materials
5. Maintained thumb length

Secondary outcome

na

Study description

Background summary

A variety of different treatment modalities are available for osteoarthritis of the CMC joint of the thumb. Until today, no differences between these different surgical treatment modalities have been proven. The objective of the current study is to investigate the outcome after pyrocarbon disc interposition for CMC thumb joint osteoarthritis in a retrospective cohort study

Retrospective clinical cohort study

Study objective

Retrospective evaluation of the long term results after treatment of thumb base osteoarthritis with a pyrocarbon disc.

We want to enroll this study in the Jeroen Bosch Ziekenhuis in 's Hertogenbosch and in the University Medical Center in Utrecht because there has been operated one of the largest series of patients treated with an pyrocarbondisc with already a long follow up period. H

Study design

Retrospective clinical cohort study

Study burden and risks

na

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

painful CMC 1 osteoarthritis at initial presentation
Type II en type III according to Eaton's classification on x-ray at initial presentation
minimum of 3 months nonsurgical treatment before treatment with operation
treated with pyrocarbon disc interposition

Exclusion criteria

STT osteoarthritis (type IV on Eaton's classification) at initial presentation
hyperlaxity (syndromes)
systemic degenerative poly or panarthrititis (RA, gout, psoriasis)

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated): 14-06-2017

Enrollment: 227

Type: Actual

Ethics review

Approved WMO

Date: 01-05-2017

Application type: First submission

Review commission: METC Brabant (Tilburg)

Approved WMO	
Date:	23-08-2017
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	21-12-2017
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL60003.028.16