

# Long term follow up of randomised clinical trial on total joint arthroplasty or trapeziectomy for trapeziometacarpal osteoarthritis

Published: 24-11-2015

Last updated: 19-04-2024

To determine if total joint arthroplasty leads to better results than trapeziectomy in the long term, with subjective and objective outcome measures.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Joint disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON42533

### Source

ToetsingOnline

### Brief title

Long term follow up of total joint arthroplasty vs. trapeziectomy

### Condition

- Joint disorders

### Synonym

trapeziometacarpal osteoarthritis; carpometacarpal osteoarthritis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Isala Klinieken

**Source(s) of monetary or material Support:** Subsidie van Isala

## Intervention

**Keyword:** Osteoarthritis, Thumb, Total joint arthroplasty, Trapeziectomy

## Outcome measures

### Primary outcome

Is there a difference in daily hand function between patients with a total joint arthroplasty and patients with a trapeziectomy, measured with the Patient Rated Wrist/Hand Evaluation (PRWHE) and the Disabilities of Arm Shoulder and Hand (DASH)?

### Secondary outcome

- Is there a difference in daily hand function between patients with a total joint arthroplasty and patients with a trapeziectomy, measured with the Disabilities of Arm Shoulder and Hand (DASH)?
- Is there a difference in pain between patients with a joint arthroplasty and a trapeziectomy?
- Is there a difference in grip strength between patients with a joint arthroplasty and a trapeziectomy?
- Is there a difference in thumb mobility between patients with a joint arthroplasty and a trapeziectomy?
- Is there a difference in complication rate between patients with a joint arthroplasty and a trapeziectomy?

- Is there a difference in the number of patients that would choose the same operation again in the same circumstances between patients with a joint arthroplasty and a trapeziectomy?

## Study description

### Background summary

Trapeziometacarpal osteoarthritis is a common cause of pain and loss of hand function in postmenopausal women. Many surgical treatments have been described and recent literature has shown that the relatively simple trapeziectomy gives equal results and less complications, when compared to other techniques such as ligament reconstructions and interpositions. A relatively new treatment modality, which has been further developed in recent years is the total joint arthroplasty. Randomized prospective trials and long-term results are lacking, but prospective cohorts show a faster recovery and good results after one year, without an increase in complication rate.

### Study objective

To determine if total joint arthroplasty leads to better results than trapeziectomy in the long term, with subjective and objective outcome measures.

### Study design

Follow up study of a randomised clinical trial (observational)

### Study burden and risks

The x-ray has a minimal radiation exposure.

The measurements of strength and mobility are not physically demanding and only take some time to fulfil.

The survey will be filled out by the researcher at the time of the consultation, so that everything will be finished when the patients leave the hospital.

Alltogether this minimizes the burden of the patient.

## Contacts

**Public**

Isala Klinieken

Dr. van Heesweg 2

Zwolle 8025 AB

NL

**Scientific**

Isala Klinieken

Dr. van Heesweg 2

Zwolle 8025 AB

NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Participation in randomised clinical trial on trapeziometacarpal osteoarthritis in the past

### Exclusion criteria

not willing to participate

past away

## Study design

## Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

## Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-11-2015

Enrollment: 55

Type: Anticipated

## Ethics review

Approved WMO

Date: 24-11-2015

Application type: First submission

Review commission: METC Isala Klinieken (Zwolle)

## 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	NL54764.075.15