

Trapeziectomy with ligament reconstruction (Weilby vs Burton Pellegrini technique) for patients with primary CMC I arthritis: a Randomised Clinical trial

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The objective of this study is to determine which operation technique is better in terms of pain, physical function, range of motion, strength and complications.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33631

Source

ToetsingOnline

Brief title

Trapeziectomy with ligament reconstruction.

Condition

- Other condition

Synonym

joint degeneration of the thumb, Thumb arthritis

Health condition

artrose

Research involving

Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht

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

Intervention

Keyword: Burton Pellegrini Technique, CMC I arthritis, thumb arthritis, trapeziectomy with ligament reconstruction, Weilby technique

Outcome measures

Primary outcome

Are there subjective differences between the two groups in functional activities of daily living 12 months after surgery?

The 'Patient Rated Wrist/Hand Evaluation - Dutch Language Version* (PRWHE-dlv) and the *Disabilities of the arm, Shoulder, and Hand - Dutch Language Version (DASH-dlv) outcome data collection instruments are used.

Is there significantly less operation time in the Weilby group.

The operation time is measured as the mean arm tourniquet time used during the procedure.

Secondary outcome

Differences in pain 12 months after surgery: using the PRWHE-dlv pain subscale.

Differences in strength 12 months after surgery: using E-link

strength-measurement-system measuring the tip pinch strength, Key pinch strength, Three-point pinch strength and grip strength.

Differences in mobility of the thumb 12 months after surgery: based on IP joint flexion/extension; MCP-joint flexion/extension; CMC-joint: palmar abduction measured using the intermetacarpal distance (IMD: the thumb is placed in full palmar abduction, the easily identifiable middorsal points on the subcutaneous surface of the first and second metacarpal heads are marked and the separation between these is measured in millimetres), opposition measured using the Kapandji score and extension measured how much the tip of the thumb can be elevated in millimetres with the hand flat on the table and the thumb in maximal radial abduction.

Differences in complications 12 months after surgery: during 12 months all complications after surgery are scored.

Study description

Background summary

Osteoarthritis (OA) at the base of the thumb can cause severe pain, weakness and/or deformity that significantly interferes with patients activities of daily living (ADL). It is a common problem, particularly in women in the fifth to seventh decades of life. A great variety of operation techniques is described during the last decades and it is therefore difficult to decide which surgical technique is indicated for each patient. The overall results of the different operation techniques in the literature are good, but problems may not have been noticed due to the relatively short follow-up. Superiority of one technique over another in terms of pain, physical function, range of motion or strength is without supporting evidence based on the present literature. We think

however that although superiority at present is without evidence, that there must be differences between the various surgical procedures, certainly in the long-term. Therefore more randomized prospective studies comparing different treatment options should be performed, with standardized methods to measure preoperative and postoperative outcomes. In this randomised clinical trial we compare two widely used operation techniques: the trapeziectomy with the ligament reconstruction described by Weilby and by Burton Pellegrini

Hypothesis: There are no differences between the two groups 12 months after operation in terms of difficulties during daily life.

Study objective

The objective of this study is to determine which operation technique is better in terms of pain, physical function, range of motion, strength and complications.

Study design

a randomised clinical trial.

Intervention

In this randomised clinical trial we compare two widely used operation techniques: the trapeziectomy with the ligament reconstruction described by Weilby and by Burton Pellegrini

Study burden and risks

During this study a total of 3 measurement sessions for each patient is indicated (preoperative, 3 months postoperative and 12 months postoperative). Each session takes approximately 30 minutes.

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

woman 40 >= years patient is diagnosed with primary CMC I arthritis and planned for operation Right and left handed one or both hands are involved CMC I Arthritis Eaton and Glickels classification IV

Exclusion criteria

man: CMC I Eaton and Glickels classification type I, II and III); Operations for CMC I arthritis in history; secondary CMC I arthritis; Muscle, neurological or other problems that could influence the postoperative management. patients who cannot complete the randomisation procedure Less knowledge of the dutch language psychiatry in history

Study design

Design

Study type: Interventional

Masking:

Double blinded (masking used)

Control:

Uncontrolled

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 02-03-2009
Enrollment: 100
Type: Actual

Ethics review

Approved WMO
Date: 10-02-2009
Application type: First submission
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL25869.100.08