Volar or dorsal approach for the proximal row carpectomy: a randomized clinical multi-centre trial

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Evaluation of the approach, both volar and dorsal: By means of function of the wrist, pain scores, complications and extra surgery.

Ethical review	Not approved
Status	Will not start
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON30413

Source
ToetsingOnline

Brief title
Approach of the proximal row

Condition

- Joint disorders

Synonym
lunate and triquete, resection of the proximal row; extirpation of the scaphoid

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: carpal instability, proximal row carpectomy, volar approach, wrist

Outcome measures

Primary outcome

Evaluation of both means (volar and dorsal). Comparison of pre- and postoperative results: range of motion, grip strength, VAS painscore and DASH score.

Secondary outcome

Adhesions is measured by restricted flexion and slow progression.

Displacement of the head of the capitate to ulnar is measured by means of radiographs.

Study description

Background summary

A proximal row carpectomy (scaphoid, lunate, triquete) is excised for different reasons. Usually, surgery is performed by means of a dorsal approach. Since 2004, the volar approach is used for proximal row carpectomies at the university hospital of Utrecht. We expect more adhesions and therefore extra surgery through the dorsal approach.

Study objective

Evaluation of the approach, both volar and dorsal: By means of function of the wrist, pain scores, complications and extra surgery.

Study design

Prospective, randomised, clinical multi-centre trial.

Intervention

One group will undergo the proximal row carpectomy by means of a volar approach and the other group by means of the dorsal approach.

Study burden and risks

Both groups will undergo the same operation. Only the approach is different. Both methods are being excised in Dutch hospitals. The extent of the burden exists of only an extra postoperative screening and radiographs. For this reason, we do not expect mental of physical stress or damage for any of the groups.

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

Will-competent adults who consider proximal row carpectomy.

Exclusion criteria

Degenerative disorders of the lunate fossa or capitolunate joint

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Not approved

Date:	13-06-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL11323.041.06