Corrective osteotomy with virtual planning of malunited forearm fractures with and without the use of patient specific guides: a randomized controlled trial

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With this study we try to answer the following question:What is the clinical outcome after a corrective osteotomy of a forearm malunion when we virtually plan the correction preoperatively and whether or not use patient-specific guides...

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

Summary

ID

NL-OMON48052

Source ToetsingOnline

Brief title 3DOOM II

Condition

Bone and joint therapeutic procedures

Synonym

angulated arm after fracture, Malunited fracture

Research involving

Human

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Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam **Source(s) of monetary or material Support:** Ministerie van OC&W

Intervention

Keyword: 3-Dimensional, Forearm, Fracture, Osteotomy

Outcome measures

Primary outcome

• Postoperative improvement in pronation and supination.

Secondary outcome

- Possibility to use boneMRI for the planning of the osteotomy.
- Postoperative improvement in subjectively experienced limitations.
- Postoperative reduction of pain.
- Postoperative improvement of cosmetics.
- Postoperative satisfaction.
- Usefulness of preoperative MRI for imaging of soft tissue scarring.

Study description

Background summary

Although a malunited fracture of (one of) the bones of the forearm can be disabling in terms of pain, loss of function and cosmetics, treatment is not yet sufficiently predictable. Patients are often young and their arm can not be fully used in daily life. In an earlier pilot study, we performed surgical correction of the fracture in 15 patients. Surgery was preoperatively planned using specially developed computer software. Also patient-specific drill and saw guides were used.

The first results of this earlier study are very promising. All operated patients are satisfied with the result of the surgery. In the current study, we want to find out the added value of patient-specific guides above the virtual

3-dimensional planning.

Study objective

With this study we try to answer the following question:

What is the clinical outcome after a corrective osteotomy of a forearm malunion when we virtually plan the correction preoperatively and whether or not use patient-specific guides peroperatively?

Study design

A randomized controlled pilot study with a one year follow-up.

Intervention

Corrective osteotomy of radius and/or ulna.

Study burden and risks

Patients will have the standard risks associated with surgery. They will also have radiation exposure from the X-rays (pre- and postoperative) and the CT scan (preoperative).

The extra load for patients participating in the study in comparison to patients not participating are:

- An additional CT scan 1 year postoperatively (extra radiation 0.4 mSv).

- Time load for filling in questionnaires at 4 time moments and extensive physical examination.

- An MRI scan is usually not made preoperatively.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years) Adolescents (16-17 years) Adults (18-64 years) Children (2-11 years) Elderly (65 years and older)

Inclusion criteria

- Malunion after radius and/or ulna fracture
- Less than 50 degrees of pronation and/or supination
- Complaints of the forearm
- Age of at least 6 years
- Full consolidation of the fractures
- Informed consent for participation in the study

Exclusion criteria

- Relevant deviations of the contralateral arm

Study design

Design

Study type: Interventional	
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

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Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	16-07-2019
Enrollment:	30
Туре:	Actual

Medical products/devices used

Generic name:	Mimics Medical software en patient specific osteotomy
	guides
Registration:	No

Ethics review

Approved WMO	
Date:	21-05-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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 CCMO **ID** NL68650.078.19

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