3D Osteotomy of Forearm Malunion

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22440

Source
Nationaal Trial Register

Brief title
3DOOM II

Health condition

Malunited fracture of radius and/or ulna

Sponsors and support

Primary sponsor: Department of Orthopedic surgery Erasmus MC
Source(s) of monetary or material Support: Department of Orthopedic Surgery Erasmus MC

Intervention

Outcome measures

Primary outcome

- Postoperative improvement in forearm rotation

Secondary outcome

- Postoperative improvement in subjectively experienced limitations
- Postoperative reduction of pain

- Postoperative improvement of cosmetics
- Postoperative satisfaction

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

Our hypothesis is that we can achieve comparable clinical outcomes with accurate virtual 3D planning and surgical preparation only.

Study design

Baseline and 3, 6 and 12 months postoperative

Intervention

Corrective osteotomy of radius and/or ulna with or without the use of patient specific guides

Contacts

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Eligibility criteria

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
- Malunion of distal radius
- Insufficient understanding of the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2019
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	30-09-2019
Application type:	First submission

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
NTR-new	NL8059
Other	METC Erasmus MC : MEC-2019-0025

Study results