# Functional improvement in forearm malunion by minimally-invasive stepwise treatment

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The aim of this study is to investigate whether a minimally-invasive stepwise treatment leads to sufficient improvement of forearm rotation in patients with malunion after fracture of the radius and/or ulna.

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

# Summary

### ID

NL-OMON56648

**Source** ToetsingOnline

Brief title 3DOOM III

### Condition

• Bone and joint therapeutic procedures

**Synonym** angulated arm after fracture, Malunited fracture

# Research involving

Human

### **Sponsors and support**

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

### Intervention

Keyword: Forearm, Fracture, Osteotomy, Three-dimensional

### **Outcome measures**

#### **Primary outcome**

Postoperative improvement in pronation and supination.

#### Secondary outcome

Postoperative improvement in subjectively experienced limitations.

Postoperative reduction of pain.

Postoperative improvement of cosmetics.

Postoperative satisfaction.

# **Study description**

#### **Background summary**

A fracture of the forearm (radius and/or ulna) is one of the most common fractures in children. Fractures with significant displacement are repositioned, and all fractures are stabilised with pins and/or cast to achieve fracture healing. In 30% of children treated with cast only, secondary displacement of the fracture occurs. If this displacement is not corrected, a malunited fracture occurs.

A malunion can cause functional impairment in addition to pain and cosmetic complaints. In many cases, this limitation consists of no longer being able to (fully) rotate the forearm, which can cause much discomfort in daily life. The standard treatment is a corrective osteotomy of both the radius and ulna using three-dimensional printed patient-specific guides to correct the alignment of the bones. This is a major procedure involving a lengthy rehabilitation period and large scars. Using four-dimensional techniques, we can now better predict what causes the rotational restriction: too-tight soft tissue or bone impingement. In the case of too-tight soft tissue (central ligament between radius and ulna), it may be sufficient to cut this ligament, while in the case of bone impingement, it may not always be necessary to correct both bones. Because restoration of function is more critical for a patient than the restoration of the exact pre-traumatic anatomy, in this study, we will make an individual treatment plan for each patient that is as minimally invasive as possible. This is the minimally invasive stepwise treatment. As an escape, a peroperative two-bone corrective osteotomy with patient-specific guides can always be performed, which is the standard treatment.

#### **Study objective**

The aim of this study is to investigate whether a minimally-invasive stepwise treatment leads to sufficient improvement of forearm rotation in patients with malunion after fracture of the radius and/or ulna.

#### Study design

Prospective pilot study with a one year follow-up

#### Intervention

Patients are treated using a minimally-invasive stepwise treatment.

#### 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 scans.

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 the questionnaires at 4 timepoints and physical examinations.

# Contacts

#### Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

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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)

### **Inclusion criteria**

Malunion after radius and/or ulna fracture Less than 50 degrees of pronation and/or supination Complaints of the forearm 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
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

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# Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	20-03-2024
Enrollment:	30
Туре:	Actual

### Medical products/devices used

Generic name:	Mimics Medical software
Registration:	Yes - CE intended use

# **Ethics review**

Approved WMO	
Date:	07-03-2024
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** Other CCMO **ID** NL6324 en NL8059 NL85062.078.24

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