Three dimensional corrective osteotomy of malunited both bone forearm fractures

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

Summary

ID

NL-OMON47030

Source
ToetsingOnline

Brief title
3DCO

Condition

- Bone and joint therapeutic procedures

Synonym
angulated arm after fracture, malunited fractures

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: 3-dimensional, forearm, fracture, osteotomy

Outcome measures

Primary outcome

The aim of this study is to increase the predictability of these difficult

procedures which hopefully result in less pain in combination with better

function and cosmetics.

primary outcome:

Improvement of pronation and supination postoperatively.

Secondary outcome

secundary outcomes:

* Reduced pain postoperatively (VAS score).

* Better cosmetics postoperatively (VAS score).

* Relation between radiological and clinical outcomes.

* Accuracy of MRI as a tool of preplanning a corrective osteotomy.

* MRI preoperatively to find soft tissue scars

* Accuracy of *true angulation* on X-ray compared to CT

Study description

Background summary

Both-bone forearm fractures are common in children. Displaced fractures need to be reduced and all fractures need to be stabilized with pins and/or cast. In 30

percent of children treated in cast secondary fracture displacement occur. This fracture displacement might result in malunited fractures with complaints of pain, limitation of function and cosmetics.
The treatment of a symptomatic malunited forearm fracture consists of a corrective osteotomy. These corrective osteotomies are very difficult to plan and operate and therefore few (orthopedic) surgeon do these procedures.
In this study, preoperative 3-dimensional planning of the corrective osteotomy is based on the mirrored normal anatomy of the non-fractured forearm and results in silicon mals which are used during surgery.

Study objective

The aim of this study is to increase the predictability of these difficult procedures which hopefully result in less pain in combination with better function and cosmetics.

Objectives:
Accuracy of corrective osteotomy
Does a corrective osteotomy result in less pain, better function and better cosmetics?

Study design

Inclusion of patients with a symptomatic malunited forearm fractures in which consersative treatment failed.
preoperative and 6 months and 1 year postoperative:
- Promis itembank lichamelijk functioneren bij kinderen - bovenste extremiteit
- Abilhand kids score
- Quick DASH score
- Painscore: VAS
- Cosmetic: VAS.

preoperative and 6 months and 1 year postoperative:
function of arm: flexion and extension of wrist and elbow, ulnar en radial deviation wrist, pronation and supination
DRUJ stability test
sqeeuze-test with Jamar Hydraulic Hand Dynamometer.

radiology
conventional X-rays pre- and postoperatively
CT-scan of both forearms preoperatively and 1 year postoperatively.
MRI-scan of both forearm preoperatively

Intervention

corrective osteotomy

Study burden and risks

CT-scan of both forearms postoperative extra (0.2mSv (Sievert)
It takes time for the patient (questionnairres, MRI, examination)

benefit: shorter surgical time, better accuracy of corrective osteotomies and better function and cosmetics of the traumatized forearm.

Contacts

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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

malunited both-bone forearm fractures with complaints of pain and/or limitation of forearm rotation.

Exclusion criteria

no pain or limitation of forearm rotation

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-08-2016
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	06-01-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-05-2018
Application type:	Amendment

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	ID
CCMO	NL52987.078.15