Refraining from closed reduction of dislocated distal radius fractures in the emergency department

Published: 27-01-2023
Last updated: 03-06-2024

The aim of this trial is to determine if CR in patients with a displaced DRF can be safely abandoned before the plaster cast, as a bridge to surgery, is applied. This could prevent a painful and traumatizing experience and therefore benefit the...

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

Summary

ID

NL-OMON53461

Source
ToetsingOnline

Brief title
RECORDED

Condition

- Bone and joint therapeutic procedures

Synonym
broken wrist, upper extremity injury

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Het onderzoek wordt gefinancïeerd vanuit het verrichtend centrum

Intervention

Keyword: closed reduction, distal radius, Emergency department, wrist fracture

Outcome measures

Primary outcome

The primary outcome is the average of the pre-operative Visual Analogue Scale for pain (VAS) score, reported on daily basis from the ED visit until operation.

Secondary outcome

Secondary outcomes are length of surgery, wrist function measured with the Patient Rated Wrist Evaluation (PRWE) score after six weeks and three, six and twelve months, length of stay in the ED, type and quantity of used pain medication, patient satisfaction and complications. Furthermore, a cost-effectiveness analysis will be performed.

Study description

Background summary

Each year, almost 26.000 adults are treated for a displaced distal radius fracture (DRF) in the Netherlands. The majority of all displaced DRFs are treated with osteosynthesis. This surgery is semi-acute planned operative care, mostly within the first week after trauma. The Dutch DRF guidelines advise to perform closed reduction (CR) of displaced DRF*s awaiting surgery at the emergency department (ED), but acknowledge that evidence supporting this advice is lacking. Meanwhile, CR is a painful, costly, time consuming procedure, often requiring anaesthesia. Most surgeons experience a substantial re-dislocation at surgery

Study objective

The aim of this trial is to determine if CR in patients with a displaced DRF can be safely abandoned before the plaster cast, as a bridge to surgery, is

applied. This could prevent a painful and traumatizing experience and therefore benefit the patient.

Study design

This study will be a multicentre cluster randomized trial. All patients will be included at the emergency department of one of the participating hospitals. Randomization at patient level will be challenging because of the 24/7 run-up of new patients at the ED at all the participating hospitals and the short time in which patients have to be included and randomized. To overcome potential protocol violations and to save precious time in the ED, randomization will take place on hospital level with a crossover point when half the aimed inclusions are reached (i.e. after 40 inclusions).

Intervention

No reduction.

Study burden and risks

The burden will consist of filling in questionaires, for which the duration will vary between 110-145 minutes for each patient.

Contacts

Public
Maasstadziekenhuis

Maasstadweg 21
Rotterdam 3079 DZ
NL
Scientific
Maasstadziekenhuis

Maasstadweg 21
Rotterdam 3079 DZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patients aged 18-75
dislocated distal radius fracture requiring plate fixation

Exclusion criteria

age <18 or >75
limb threatening injury (ischemia, compound fracture, nerve damage)
multiple trauma patients
previous injury imparing wrist function or previous fracture of ipsilateral wrist <3 months
insufficient comprehension of the dutch language of inability to complete study period (e.g. patients from abroad who will have further treament outside participating hostipals)

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:	Recruiting
Start date (anticipated):	08-05-2023
Enrollment:	134
Type:	Actual

Ethics review

Approved WMO Date:	27-01-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-02-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-05-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-10-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-05-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL81890.100.22