Blind versus Ultrasound-guided Radius Reduction STudy

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This multicentre randomised controlled trial aims to investigate whether PoCUS can be used as an adjunct to improve first attempt success rate in closed reductions of displaced distal radial fractures in adults in the ED.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON25424

Source
NTR

Brief title
BURRST

Condition

- Bone and joint therapeutic procedures

Synonym
Distal radial fracture, distal radius fracture, ultrasound, PoCUS, closed reduction

Health condition

Distal radius fracture

Research involving
Human

Sponsors and support

Primary sponsor: MCL
Source(s) of monetary or material Support: SGO-fund

Intervention

- Medical device

Explanation

Outcome measures

Primary outcome

A 50% reduction in repeated reduction attempts of distal radius fractures between the ultrasound guided group and the control group.

Secondary outcome

The difference between both groups in the number of patients that need reduction in operating theater, the difference in reduction time in ED between both groups.

Study description

Background summary

During closed reduction of displaced distal radial fractures, physicians have to rely on physical examination to determine the need for further reduction before cast application. Point-of-care ultrasound (PoCUS) has the potential to inform physicians about the outcome of the reduction even before obtaining a post-reduction X-ray or cast application. This may decrease the number of reduction attempts.

Study objective

This multicentre randomised controlled trial aims to investigate whether PoCUS can be used as an adjunct to improve first attempt success rate in closed reductions of displaced distal radial fractures in adults in the ED.

Study design

Multicentre randomised controlled trial

Intervention

Ultrasound

Study burden and risks

The use of ultrasound does not cause any risk for patients included.

Contacts

Public
MCL
Svenja Haak

Scientific
MCL
Svenja Haak

Eligibility criteria

Age
Adolescents (16-17 years)
Adolescents (16-17 years)
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

Patients more than 16 years of age with a distal radius fracture (including intra-articular fractures or in combination with a distal ulna fracture) with significant displacement that requires reduction.

Exclusion criteria

Age <16 years, open fractures, new neurovasculair damage, operation indication based on first X-ray, osteosynthesis material in fractured wrist, a reason that makes it impossible to applicate ultrasound gel.

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2018
Enrollment:	214
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	24-09-2018
Application type:	First submission
Review commission:	Regionale Toetsingscommissie Patiëntgebonden Onderzoek Postbus 888 8901 BR Leeuwarden 058 286 1151 RTPO@mcl.nl

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	NL7934
Other	METC MCL, METC Isala, METC UMCG : Not-WMO, RTPO 1050

Study results

Results posted: 21-06-2023

Actual enrolment: 211

Summary results
This multicentre randomised controlled trial could not demonstrate that PoCUS guided reduction of distal radial fractures was associated with a lower number of reduction attempts or a lower proportion of patients with an indication for operative repair.

Baseline characteristics
Demographics and fracture characteristics were similar in both treatment groups, except there are slightly more patients with an associated ulnar fracture in the standard group

Participant flow
A total of 105 patients were randomised to the standard treatment group, and 106 patients to PoCUS guided fracture reduction.

Adverse events
None