Blind versus Ultrasound-guided Radius Reduction STudy

Published: 05-08-2019 Last updated: 03-05-2024

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.

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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

NI

Recruitment stopped
12-01-2018
214
Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion Date: Application type: Review commission:

24-09-2018 First submission

Deviewels Tes

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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