

THE USE STUDY Can Ultrasound Safely exclude Elbow fractures?

Published: 13-11-2020

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To establish the diagnostisch accuracy of ultrasound for the exclusion of fracture of the elbow

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Observational non invasive

Summary

ID

NL-OMON25266

Source

Nationaal Trial Register

Brief title

USE

Condition

- Bone and joint injuries

Health condition

suspected elbow fracture

Research involving

Human

Sponsors and support

Primary sponsor: SGO

Source(s) of monetary or material Support: - Medisch Centrum Leeuwarden

- Applied for funding by SGO fund of NVSHA

Intervention

- Medical device

Explanation

Outcome measures

Primary outcome

Sensitivity of ultrasound for elbow fractures

Secondary outcome

- Positive predictive value of ultrasound for elbow fractures - Negative predictive value of ultrasound for elbow fractures - Specificity of ultrasound in elbow fractures

Study description

Background summary

In current practice fracture of the elbow is made based on physical examination and radiography.

Compared to radiography, ultrasound is bed-side available, has lower costs and has no radiation exposure. Point-of-care ultrasound of the elbow might be a good alternative to X-rays to rule out fractures of the elbow.

Study objective

To establish the diagnostic accuracy of ultrasound for the exclusion of fracture of the elbow

Study design

prospective, multi-center, observational cohort study

Intervention

ultrasonography

Study burden and risks

Patients are not exposed to any risks as results of this study, patients might experience mild pain during ultrasound of the elbow.

Contacts

Public

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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

Patiënts \geq 16 years old who present to the ER with a suspected elbow fracture.

Exclusion criteria

- Extensive additional injury; high-energy trauma with multiple injuries, neurotrauma, accompanying thoracic injury, and /or hemodynamic instability - Open fractures - Luxation fractures, when suspected on physical examination - Clinically diagnosed new neurovascular damage - Osteosynthesis material in situ at affected elbow - No informed consent from the patient - Patients coming to the emergency room from the radiology department with a proven fracture of the elbow or a positive fat pad sign on X-ray

Study design

Design

Study phase: N/A

Study type: Observational non invasive

Intervention model: Other

Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2021
Enrollment:	215
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion	
Date:	01-08-2020
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	NL9046
Other	RTPO : RTPO 1101

Study results