Diagnosing clavicle fractures without radiation: is ultrasound helpful?

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28705

Source
NTR

Brief title
CRUSH

Health condition

Clavicle fracture

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Diagnostic accuracy of POCUS for diagnosing a clavicle fracture in ED.

Secondary outcome

- Difference in primary outcome between children and adults.

- Level of agreement (kappa) between dislocation measured on X-ray and measured by POCUS.
- Correlation between dislocation measured on X-ray and measured by POCUS.
- Difference in discomfort during exam between POCUS and X-ray.

Study description

Background summary

Clavicle fractures are commonly seen in the ED in adults and children. Diagnosis is traditionally made based on X-ray, which exposes the patient to radiation. Ultrasound may be a radiation free alternative to X-ray. This multicenter prospective cohort study aims to evaluate the diagnostic accuracy of POCUS for suspected clavicle fractures compared to X-ray of the clavicle for all patients (≥4 years) presenting to the ED.

Study objective

Good diagnostic accuracy of POCUS for diagnosing a clavicle fracture in ED.

Study design

The ultrasound is bedside and will be evaluated straight away, the second review is done when inclusions are finished.

Contacts

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Eligibility criteria

Inclusion criteria

All patients with suspected clavicle fracture presenting to the ED.

Exclusion criteria

- Extensive other trauma (HET, neurotrauma, hemodynamically unstable)
- Age < 4 year
- Open fractures
- Neurovasculair damage
- Recent clavicle fracture same side (<3 months)
- Complaint > 7 days
- Proven clavicle fracture before POCUS
- No informed consent from patient (≥16 year) or parent(s) (<16 year)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2021
Enrollment:	170
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	16-01-2021
Application type:	First submission

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	NL9236
Other	METC MCL : nWMO 354

Study results