The HipPOCUS-trial

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25001

Source
NTR

Health condition

Proximal femur fractures

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: not applicable

Intervention

Outcome measures

Primary outcome

The main study endpoint is the diagnostic value of POCUS for hip fractures. This will be measured by measuring: the sensitivity, specificity, negative predictive value (NPV), the positive predictive value (PPV). Positive likelihood ratio (LR+) and negative likelihood ratio (LR-).

Secondary outcome

- To investigate whether the suspicion of fracture by the physician is (correctly) altered after POCUS
- To research which POCUS findings best support the presence or absence of a

fracture.
- To study which POCUS view is most suitable for determining the presence or absence of a fracture.

Study description

Background summary

Hip fractures are common in the emergency department (ED). In our region (Southern part of the Netherlands), more than 1200 hip fractures were diagnosed and admitted to the hospital in 2018. Although MRI is the gold standard in diagnosing hip fractures, X-ray with AP pelvic and lateral hip views are the first recommended diagnostics. CT-scan is indicated if the X-rays show no fracture, but the index of suspicion is high at physical examination. The development of Point Of Care Ultrasonography (POCUS) devices has led to the discovery of new applications for this tool. One of those applications is diagnosing fractures in situations where conventional methods are not easily accessible, such as prehospitally by ambulance paramedics or general practitioners. Earlier diagnosis could reduce delays and therefore patient discomfort.
The primary goal of this study is to investigate the diagnostic value of POCUS, performed by emergency physicians, as a screening tool for hip fractures. We would like to achieve that using a prospective descriptive study design. Patients who are 18 years or older presenting in the ED with a suspected hip fracture wil be included. They will undergo an additional POCUS performed by emergency physicians who are blinded for X-ray of CT-scan results. Results of POCUS will not influence standard care of participants.
The main study endpoint is the diagnostic value of POCUS for hip fractures. This will be measured by measuring: the sensitivity, specificity, negative predictive value (NPV), the positive predictive value (PPV). Positive likelihood ratio (LR+) and negative likelihood ratio (LR-).

Study objective

The sensitivity of POCUS, performed by emergency physicians is ≥ 90%

Study design

Patient admitted to the ED with suspicion of a hip fracture will be screened as potential candidates. When inclusion criteria are met and when the patient has given consent the patient will be included in the study. Patients will then receive the ultrasound exam of their hip. The exam will be performed by a blinded experienced emergency physician or emergency medicine resident. The local protocol for hip fractures will be followed for all patients. Written informed consent will be obtained within 24 hours. A follow up of one-month will take place by studying the included patients’ medical dossier in order to track for any potentially missed fractures.

ED physician or ED resident will be asked to put on a scale between 1 to 10 how the high his index of suspicion is before and after the POCUS where 1 is the lowest suspicion and 10 the highest suspicion.

The ED physician or ED resident will document
1. The POCUS findings supporting presence or absence of hip fracture:
No abnormal findings
Cortex:
- Intact
- Cortical breach along the femoral neck
- Cortical breach along the trochanter major or minor.
- Step-off deformity along the femoral neck
Presence of joint and bursal effusions, intra-articular fluid based on:
- No fluid
- Anterior displacement of the iliofemoral ligament by a fluid collection
- Separation of the anterior and posterior layers of the joint capsule
- Capsule-to-bone distance greater than 3mm
Peri trochanteric hematoma or oedema, based on:
- Hypoechoic fluid collection around the greater trochanter
- Heterogeneous soft tissue swelling around greater trochanter

2. Best POCUS view obtained for diagnosis:
Anteriorly
Laterally
Other view to be described

All values will be described as percentages with a 95% confidence interval. Statistical significance shall be examined using the z-test for binair variables. One sample t-test will be used for continual variables. p value of 0,05 or lower will be considered statistically significant. Analysis will be performed by IBM SPSS Statistics 21.
We will describe the index of suspicion of hip fracture (correctly) altered after POCUS and the POCUS findings and best view those where obtained with descriptive statistics.

Intervention

When inclusion criteria are met and when the patient has given consent the patient will be included in the study. Patients will then receive the ultrasound exam of their hip. The exam will be performed by a blinded experienced emergency physician or emergency medicine resident. The local protocol for hip fractures will be followed for all patients. Written informed consent will be obtained within 24 hours. A follow up of one-month will take place by studying the included patients' medical dossier in order to track for any potentially missed fractures.

Contacts

Public

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Eligibility criteria

Inclusion criteria

1. 18 years old or older.
2. Suspicion of proximal femur fracture.

Exclusion criteria

1. Open fractures.
2. Unavailability or technical issues of the ultrasound device.
3. Hip fracture already diagnosed before patient arrival to the ED.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	05-01-2021
Enrollment:	80
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	21-09-2020
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	NL8935
Other	METCZ Zuyderland - Zuyd : METCZ20200133

Study results