

The HipPOCUS-trial

Gepubliceerd: 21-09-2020 Laatste bijgewerkt: 18-08-2022

The sensitivity of POCUS, performed by emergency physicians is $\geq 90\%$

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25001

Bron

Nationaal Trial Register

Aandoening

Proximal femur fractures

Ondersteuning

Primaire sponsor: none

Overige ondersteuning: not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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-).

Toelichting onderzoek

Achtergrond van het onderzoek

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 prehospital 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 will be included. They will undergo an additional POCUS performed by emergency physicians who are blinded for X-ray or 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-).

Doel van het onderzoek

The sensitivity of POCUS, performed by emergency physicians is $\geq 90\%$

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland Status:	Werving nog niet gestart
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(Verwachte) startdatum: 05-01-2021
Aantal proefpersonen: 80
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 21-09-2020
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8935
Ander register	METCZ Zuyderland - Zuyd : METCZ20200133

Resultaten