Additional clinical value of routine CT-imaging in fragility fractures of the pelvis; a prospective cohort study

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Routine CT-scanning of the pelvis in (suspected) ramus inferior/superior fractures in the elderly will lead to significant alternations of treatment strategies with regards to the number of patients receiving operative treatment, a more restrictive...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27564

Bron
Nationaal Trial Register

Verkorte titel
ARTIFACT

Aandoening

Fragility fractures of the pelvis in elderly patients

Ondersteuning

Primaire sponsor: Noordwest Ziekenhuisgroep, Department of Surgery
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percentage of change in treatment strategy based on the pelvic CT-scanning (operative intervention, admission, outpatient clinical follow-up, change in mobilisation policy)

Toelichting onderzoek

Achtergrond van het onderzoek

Fragility fractures of the pelvis (FFP) in elderly patients are an underestimated injury with a significant impact on mobility, independency and mortality similar to hip fracture patients.These isolated anterior pelvic ring fractures are stable fractures that often do not require surgical intervention and patients can be treated with pain guided mobilization. However, a concomitant posterior pelvic ring fracture (cPRF's) in the form of a sacral fracture is often found when properly looked for. For adequate detection, Computed Tomograhpy (CT) or Magnetic Resonance Imaging (MRI) scanning is used. In previous studies that use routine additional CT or MRI imaging, high rates of cPRF's are found ranging between (59%-96,8%). Previous studies advise routine pelvic CT-scanning for every patient with pubic rami fractures because of the high cPRF detection rate and is considered standard therapy. However, the clinical consequences of this routine CT-imaging have not yet been established. Because of this lack of knowledge, incomplete evidence based protocols exist for FFP's. Further studies are needed to establish the additional clinical value of routine CT imaging in fragility fractures in order to establish definitive evidence based diagnostic and treatment schemes. This study will establish the additional clinical value of routine imaging in FFP patients sustaining a low energy trauma by studying the number of treatment alterations due to the pelvic CT-scan by taking questionnaires with the treating trauma- or orthopedic consultant with regards to the treatment pre- and post CT-scan and questionnaires for the patients with regards to pain, quality of life and mobilization ability over time.

Doel van het onderzoek

Routine CT-scanning of the pelvis in (suspected) ramus inferior/superior fractures in the elderly will lead to significant alternations of treatment strategies with regards to the number of patients receiving operative treatment, a more restrictive ambulation policy in the post-trauma period, hospital admission and/or more intensive outpatient clinical follow-up.

Onderzoeksopzet

Day one, seven, 28 and 90 post after trauma

Onderzoeksproduct en/of interventie

No interventions with regards to patient care will be performed in this study. Outcome will be measured via questionnaires that are completed by treating physicians and patients.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients admitted to the ED with a (suspected) pubic rami fracture
- Aged ≥ 65 years old
- Sustaining a low-impact injury
- Able to provide a written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- High Energetic Trauma (HET) patients
- Insufficient understanding of the Dutch language

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2019
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	02-09-2019
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	NL8011
Ander register	METC VUmc : 2019.495

Resultaten

Samenvatting resultaten
None yet; study is ongoing