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

No registrations found.

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

Summary

ID

NL-OMON27564

Source
Nationaal Trial Register

Brief title
ARTIFACT

Health condition

Fragility fractures of the pelvis in elderly patients

Sponsors and support

Primary sponsor: Noordwest Ziekenhuisgroep, Department of Surgery
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- Additional fractures found on pelvic CT-imaging (number of posterior ring fractures, additional ramus fractures, occult acetabular fractures).
- Sensitivity/specificity of physical examination
- Mortality, complications during the 3 month's follow-up
- Number of operative interventions
- Mobility during the follow-up period (day 1,7,28 and 90)
- Institutionalizations (number of patient temporary or definitive admission to rehabilitation clinics or nursing homes post-hospital discharge)
- Pain scores (NRS) (during mobilization and rest) and analgesic use (after day 1, 7, 28 and 90)
- Quality of Life (EQ-5D) (day 1, 7, 28 and 90)

Study description

Background summary

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.

Study objective

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.

Study design

Day one, seven, 28 and 90 post after trauma

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

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

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:	Recruitment stopped
Start date (anticipated):	01-10-2019
Enrollment:	50
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Positive opinion

Date:	02-09-2019
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	NL8011
Other	METC VUmc : 2019.495

Study results

Summary results
None yet; study is ongoing