Long-term musculoskeletal function after Open PElvic ring fractures in Children (OPEC); a multicenter, retrospective case series with follow-up measurement

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The primary aim of this study is to assess the long-term musculoskeletal function (Short Musculoskeletal Functional Assessment, SMFA) in patients who sustained an open pelvic ring fracture when they were aged

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Observational non invasive

Summary

ID

NL-OMON50499

Source
ToetsingOnline

Brief title
OPEC; Outcome of open pelvic ring fractures in children

Condition

- Bone and joint injuries

Synonym
Open pelvic ring fracture; Fractured pelvis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Open fracture, Outcome, Pedicatric, Pelvis

Outcome measures

Primary outcome

Musculoskeletal function (SMFA).

Secondary outcome

- The presence of growth disorders

- Urogenital function (VSSDES)

- Sexual dysfunction (IIEF-5 in males and FSFI in females)

- Motor function of the lower extremities (MRC scale)

- Sensory function of the lower extremities (soft touch and pin prick test for

gnostic and vial sensitivity, respectively).

Study description

Background summary

Pelvic ring fractures are relatively uncommon in the pediatric population (0.3-7.5% of all pediatric fractures). Open pediatric pelvic ring fractures are even more rare. Little or no data are available about the musculoskeletal function, growth deformities, and neurological and urogenital function after (non)operative treatment of open pelvic ring fractures. No specific case series have been described in literature.

Study objective

The primary aim of this study is to assess the long-term musculoskeletal function (Short Musculoskeletal Functional Assessment, SMFA) in patients who sustained an open pelvic ring fracture when they were aged <18 years. The secondary aims are to assess in these patients: 1) growth disorders (pelvic X-ray); 2) urogenital function (Vancouver Symptom Score for Dysfunctional

Elimination Syndrome, VSSDES); 3) sexual dysfunction (International Index of Erectile Function, IIEF-5, for males and Female Sexual Function Index, FSFI, for females; 4) motor function of the lower extremities (Medical Research Council, MRC, scale); and 5) sensory function of the lower extremities (soft touch and pin prick test for gnostic and vial sensitivity, respectively).

Study design

Multicenter, retrospective case series with follow-up measurement.

Study burden and risks

Participants should not expect any personal benefits from their participation in this study, but their participation may help future patients. There are only negligible risks associated with this study. Patients will be invited for a single follow-up visit at the outpatient department. During the visit, single X-ray of the pelvis will be made, and the sensomotoric function of a leg will be assessed. In addition, patient will be asked to complete three short questionnaires on musculoskeletal function, urinary incontinence, and (if 18+ years) sexual dysfunction, which will take approximately 30 minutes. Besides this, already existing data will be collected from the patients* medical files and the Trauma Registry. The study is deemed to be group-related, as it cannot be conducted without the participation of subjects belonging to the group in question.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

1) Age at trauma below 18 years
2) Open pelvic ring fracture (since January 1, 2001).
3) Written informed consent by patient or parents in case patient has age below 16 years at follow-up

Exclusion criteria

1) Less than 30 days of follow-up post-trauma
2) Unknown contact details for patient *
3) Insufficient understanding of Dutch language to understand the questionnaires or other study information, in the judgement of the research team *

* Also applies to parents if the patient is <16 years at follow-up.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2022
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	13-10-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL78064.078.21