Effects of a physical therapy protocol for patients treated for acetabular fractures

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The aim of this study is to investigate the effects of a prolonged physical therapy protocol for patients treated for acetabular fractures.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON52235

Source
ToetsingOnline

Brief title
PACE

Condition

- Fractures

Synonym
Acetabular fracture, fracture of the hip socket

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Acetabular fractures, Patients, Physical therapy, Protocol

Outcome measures

Primary outcome

The primary outcome of this study is the health related quality of life.

Secondary outcome

Secondary outcomes are muscle strength, range of motion, gait pattern,

complications of the surgery and residual displacement after surgery.

Study description

Background summary

Acetabular fractures are relatively rare and occur after a high energy impact on the hip. Acetabular fractures are intra-articular fractures. Incongruency in the hip socket results in early post traumatic arthritis. Therefore, acetabular fractures should be anatomically reduced. Open reduction and internal fixation (ORIF) is the standard current treatment for these injuries.
Limited data is available regarding the impact of physical therapy on the quality of life, muscle strength, range of motion and gait pattern after surgical treatment of acetabular fractures. In our daily practice, patients start directly post-operatively with physical therapy, supervised by a specialized physical therapist. When patients can go home, physical therapy is continued by physical therapists at home, who see these injuries on a rare basis. We hypothesize that patients will benefit from a physical treatment protocol under supervision of a specialized hospital-based trauma physical therapist, which is continued during outpatient follow-up. This allows them to mobilize in a better way in comparison with regular physical therapy treatment. This might lead to an improvement of quality of life and functional outcome.

Study objective

The aim of this study is to investigate the effects of a prolonged physical therapy protocol for patients treated for acetabular fractures.

Study design

Pilot randomized controlled trial

Intervention

One group receive physical therapy as usual care after treatment of acetabular fractures. The other group will be treated with individual goals at a functional level based on the results of measurements during follow-up

Study burden and risks

The benefit of this study is the possibility that the participant will recover faster or that they will experience less pain. The disadvantage of this study is that it takes thirty minutes extra time per visit to the outpatient clinic. In our opinion, this study adds a small chance (*kleine kans*) of mild damage (*lichte schade*) and consequently adds a negligible risk (*verwaarloosbaar risico*) according to the risk classification of the *Nederlandse Federatie van Universitair Medische Centra* (NFU).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients with a fracture of the acetabulum which will be surgically treated, age 16 or older with a fully grown skeleton*
- Able to fill in online questionnaires in Dutch
- Able to give written informed consent

*When bone growth is complete, the epiphyseal cartilage is replaced with bone, which joints it to the diaphysis. This can be checked with X-rays and CT. Both examinations are part of usual care.

Exclusion criteria

- Mentally not fit to complete the questionnaire
- Not able to perform activities of daily living independently and without mobility aids before the accident
- Other injury of the spine, upper or lower extremites that affect mobilization
- No use of physical therapy after discharge
- Not treated according to the standard rehabilitation protocol (Appendix A)
- Illiteracy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-04-2021
Enrollment:	40

Type:	Actual

Ethics review

Approved WMO Date:	02-03-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-03-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL75648.091.20

Study results

Date completed:	17-06-2022
Actual enrolment:	8

Summary results
Trial ended prematurely