Dutch Research for the Evaluation of Acetabular fracture Management in 3D

Gepubliceerd: 14-04-2021 Laatst bijgewerkt: 18-08-2022

Better fracture reduction using patient-specific implants compared to conventional implants

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28665

Bron
NTR

Verkorte titel
DREAM-3D study

Aandoening

Acetabular fracture

Ondersteuning

Primaire sponsor: UMCG
Overige ondersteuning: SNN grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint is the residual fracture displacement (in mm), as measured on the postoperative CT-scan.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:
In acetabular fracture surgery, achieving an optimal reconstruction of the articular surface improves the functional outcome and decreases the risk of progressive osteoarthritis and the subsequent need for total hip arthroplasty. With the current implants, it regularly occurs that a good anatomical reduction and optimal operative fixation of the fractured acetabulum won't be achieved. Unfortunately, conventional plates often don't fit to the shape of each pelvis and don't hold the surgically reduced fracture fragments perfectly in place despite multiple intra-operative bending and contouring manoeuvres. We developed an innovative method to design, produce and apply patient-specific plates with drilling guides for acetabular fracture surgery. The aim of this study is to assess whether this approach will improve the quality of the reduction, and operative fixation, functional outcome and surgeon's efficiency compared to the conventional osteosynthesis.

Objective of the study:
To assess whether patient-specific implants for acetabular fracture surgery result in a more accurate reconstruction of the articular surface in comparison to conventional plate osteosynthesis.

Study design:
All patients who will be included in this multicentre prospective cohort study will be operated for an associated acetabular fracture with either a conventional implants (control group) or patient-specific implants (intervention group). The treatment allocation will depend on the centres in which the patient will be treated (3 Level 1 trauma centers using the conventional implants and 3 Level 1
trauma centers using the patient-specific implants). For manufacturing the patient-specific implants, CT data will be used to create a 3D computer model of the fractured pelvis. The personalised implants and drilling guides, tailored to both the shape of the pelvis and the type of fracture, will be designed and produced within a few days and finally applied during surgery.

Study population:
Patients (>18 yrs) presenting with an acute (2 weeks from the injury) displaced acetabular fracture for which a surgical intervention is indicated.

Intervention (if applicable):
The intervention group will be surgically treated with patient-specific implants and the control group will be surgically treated with conventional implants.

Primary study parameters/outcome of the study:
The primary endpoint is the residual fracture displacement (in mm), as measured on the postoperative CT-scan.

Secundary study parameters/outcome of the study (if applicable):
The secondary endpoint includes patient reported outcome, which will be assessed with validated follow-up questionnaires at oneyear
follow-up. Additionally, surgery related factors e.g. the total time for intra-operative bending manoeuvres, plate positioning and fixation, the surgeon’s satisfaction about implant fitting will be assessed. For the patient-specific implants, the accuracy of the screw positions will be assessed by matching the preoperative virtual planning with the post-operative CT images.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):
The extent of burden and risks for patients participating in the study is considered low, because the main parts of the operative procedure itself won’t change. Moreover, our pilot study with patient-specific implants for acetabular fracture surgery (N=10) demonstrated that this technique is feasible, safe and appears to be effective.

Doel van het onderzoek

Better fracture reduction using patient-specific implants compared to conventional implants

Onderzoeksopzet

Follow-up at 6 weeks, 3 months, 6 months and one year.

Onderzoeksproduct en/of interventie

The intervention group will be surgically treated with patient-specific implants and the control group will be surgically treated with conventional implants.

Contactpersonen

Publiek

UMCG
Anne Meesters

0503611885

Wetenschappelijk

UMCG
Anne Meesters

0503611885

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients ≥ 18 years with an acute (2 weeks from the injury) displaced acetabular fracture will be included after a signed informed consent.
- Associated type acetabular fracture types (posterior column and wall, transverse and posterior wall, T-type, anterior column and posterior hemitransverse, both column fractures).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Elementary acetabular fracture types (isolated posterior wall, isolated posterior column, anterior wall, anterior column and transverse fractures)
- ‘Late’ acetabular fractures more than 2 weeks after the injury
- Pathological fractures
- Patient with previous hip surgery or surgery in the pre-peritoneal space (Stoppa approach) making an anterior or posterior pelvic approach hardly possible.
- Patient unfit for acetabular surgery (e.g. anterior and posterior approach in one tempi).
- Patients with body-mass index (BMI) >35.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	19-04-2021

Aantal proefpersonen:	150
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL9399
Ander register	METC UMCG : METc 2020/086

Resultaten