

Initial results of the Anser: A novel intramedullary device for fixation of midshaft clavicle fractures.

An explorative case series

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24145

Source

NTR

Brief title

Anser Trial

Health condition

Clavicle Fractures

Sponsors and support

Primary sponsor: Radboud UMC Nijmegen

Source(s) of monetary or material Support: STW Takeoff

Intervention

Outcome measures

Primary outcome

The primary outcome measures will be union rate, complication rate and functional outcome

scores.

Secondary outcome

Secondary outcomes will be closed reduction rate, operative time, image-intensifier time, hospital stay, incision length, time to radiological union, pain, re-operation, health related quality of life and cosmetic satisfaction.

Study description

Background summary

The Anser is a novel device for the intramedullary fixation of the fractured clavicle aiming to reduce the clavicle and preserve its length in a minimally invasive manner.

The goals of this study are to evaluate the initial performance, safety and functional results of the Anser; A novel intramedullary device for fixation of midshaft clavicle fractures.

The primary outcome measures will be union rate, complication rate and functional outcome scores.

Secondary outcomes will be closed reduction rate, operative time, image-intensifier time, hospital stay, incision length, time to radiological union, pain, re-operation, health related quality of life and cosmetic satisfaction.

Prospective explorative case series. Therapeutic study. 3 Dutch hospitals are involved.

20 patients between 18 and 65 years of age with a displaced midshaft clavicle fracture type 2A2 or 2B1 according to the Robinson Classification are included once informed consent is given. Follow up will be 12 months.

Study objective

The goals of this study are to evaluate the initial performance, safety and functional results of the Anser; A novel intramedullary device for fixation of midshaft clavicle fractures.

Study design

-

Intervention

Use of the Anser Clavicle Pin for midshaft clavicle fractures.

Contacts

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Eligibility criteria

Inclusion criteria

- Displaced midshaft clavicle fracture Type 2A2 or 2B1 according to the Robinson Classification
- Age > 18 years, < 65 years
- < 10 days after trauma

Exclusion criteria

- All patients deemed not fit for surgery by the anesthesiologist
- All patients with nonunion or previous malunion
- Patients <18 years or > 65 years
- Possible noncompliant patients (eg, alcohol and drug addiction, dementia)
- Additional neurovascular injury
- Pathologic fractures

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2016
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion	
Date:	30-09-2016
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	NL6097
NTR-old	NTR6243
Other	CMO Arnhem-Nijmegen : 2016-2428

Study results