The Anser Clavicle Pin for Surgical Management of Midshaft Clavicle Fractures; A Prospective Case Series

No registrations found.

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

Summary

ID

NL-OMON25047

Source
Nationaal Trial Register

Brief title
ACP Study

Health condition

Displaced midshaft clavicle fractures

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis Arnhem
Source(s) of monetary or material Support: Isshoni BV / Anser Implants BV

Intervention

Outcome measures

Primary outcome

Functional outcome scores as measured by the Constant Murley Score (CMS) and the Disabilities of Arm, Shoulder and Hand (DASH).

Secondary outcome

Union rate, complication rate, closed reduction rate, operative time, image-intensifier time, hospital stay, post-operative pain reduction, re-operations, return to work, health related quality of life and patient satisfaction.

Study description

Background summary

The goals of this study are to evaluate the union rate, patient satisfaction and functional results of the Anser Clavicle Pin in 100 patients with displaced midshaft clavicle fractures.
The primary outcome measures are functional outcome scores as measured by the Constant Murley Score (CMS) and the Disabilities of Arm, Shoulder and Hand (DASH).
Secondary outcomes are union rate, complication rate, closed reduction rate, operative time, image-intensifier time, hospital stay, post-operative pain reduction, re-operations, return to work, health related quality of life and patient satisfaction.

Study objective

The Anser Clavicle Pin will be a viable option in the surgical management of midshaft clavicle fractures.

Study design

Preop, Operation, 1 week, 6 weeks, 3 months, 1 year

Intervention

Surgical placement of Anser Clavicle Pin

Contacts

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Eligibility criteria

Inclusion criteria

- Displaced midshaft clavicle fracture Type 2B according to the Robinson Classification
- Age ≥ 18 years
- Surgery performed within 4 weeks after trauma

Exclusion criteria

- All patients deemed not fit for surgery by the anesthesiologist
- All patients with nonunion or previous malunion
- 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):	01-01-2021
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	17-11-2020
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	NL9061
Other	CMO Arnhem-Nijmegen : CMO 2018-4053

Study results