

Treatment of midshaft clavicle fractures: plate fixation versus figure-of-eight bandage.

Submission date 28/01/2010	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 18/02/2010	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 18/02/2010	Condition category Injury, Occupational Diseases, Poisoning	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Treatment of midshaft clavicle fractures: plate fixation versus figure-of-eight bandage:
Randomised controlled clinical trial

Study objectives

There is no difference between surgical versus conservative interventions for treating midshaft clavicle fractures

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethics Committee of The Universidade Federal de São Paulo/Hospital São Paulo approved on the 29th of August 2008 (ref: CEP 0891/08 UNIFESP)

Study design

Randomised active controlled parallel group clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Clavicle fractures

Interventions

Patients will be randomised to

1. The surgical group (plate fixation):

All participants will be undergo the operation within two weeks after the injury; prophylactic antibiotics will be used. Under a general anaesthetic, the patient will be positioned in a beach-chair semi-sitting position. The involved shoulder will be prepared and draped, and an oblique incision will be made over the fracture site. The fracture site will be identified, and the fracture will be reduced and fixed with an antero-inferior plate (3.5 mm reconstruction plate). A sling will be used for comfort for seven to ten days, and then a physiotherapist will instruct the patient.

2. Figure-of-eight bandage:

In the conservative group, the figure-of-eight bandage will be used for 6 weeks, and every week the participants will return to check and adjust the immobilisation. In this way, the dominant hand can remain free and simple activities will be allowed (writing, keyboarding and other). After 6 weeks, participants will be encouraged to discard the bandage, but load bearing will not be recommended before osseous consolidation (around ten weeks).

Identical care program for rehabilitation will be done in each of compared groups. Following enrolment in the study, all the participants will be seen every week during the first 6 weeks and at 3, 6 and 12 months and all primary and secondary outcomes will be reported.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Disability of Arm Shoulder and Hand (DASH) questionnaire, assessed at 3, 6 and 12 months

Key secondary outcome(s)

1. Range of movement
 2. VAS (visual analogue scale)
 3. Cosmetic appearance, assessed at the end of the follow up period
 4. Time to consolidation
 5. Clavicular length or shortening and shift
 6. Complications / failure of treatment, monitored throughout the follow up period
- All outcomes will be assessed at 3, 6 and 12 months unless otherwise stated.

Completion date

01/01/2012

Eligibility

Key inclusion criteria

1. Adults age 18-60
 2. Patients with completely displaced middle third clavicle fractures, amenable to plate fixation with a minimum of three screws in both fragments
- Recruitment of participants will take place in emergency centres of two hospitals in Espirito Santo and Sao Paulo, Brazil.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

60 years

Sex

All

Key exclusion criteria

1. Open fractures
2. Age under 18 or over 60 years
3. Fracture in the proximal or distal clavicle
4. Fracture associated with nerve or tendon injuries
5. Multiple injuries

6. Additional fractures in the same or contra-lateral limb
7. Previous fracture of the injured clavicle
8. Abnormal function of the uninjured side
9. Inflammatory joint disease
10. Cerebrovascular disease or other severe medical illness
11. Inability to give informed consent or to complete questionnaires

Date of first enrolment

01/01/2008

Date of final enrolment

01/01/2012

Locations

Countries of recruitment

Brazil

Study participating centre

Department of Orthopaedics and Traumatology,

São Paulo

Brazil

04038-032

Sponsor information

Organisation

Universidade Federal de Sao Paulo (UNIFESP) (Brazil)

ROR

<https://ror.org/00bkgf580>

Funder(s)

Funder type

University/education

Funder Name

Universidade Federal de Sao Paulo (UNIFESP) (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration