

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

<b>Submission date</b> 28/01/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 18/02/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/02/2010	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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