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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet.

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

Secondary outcome measures
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.

Overall study start date
01/01/2008

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
120 participants

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,
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Sponsor information

Organisation
Universidade Federal de Sao Paulo (UNIFESP) (Brazil)

Sponsor details

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Sponsor type
University/education

ROR
https://ror.org/00bkgf580

Funder(s)

Funder type
University/education

Funder Name
Universidade Federal de Sao Paulo (UNIFESP) (Brazil)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration