

Conservative versus surgical interventions for treatment of the humeral shaft fractures in adults

Submission date 18/05/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 16/06/2010	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 09/08/2013	Condition category 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

Study information

Scientific Title
Surgical intervention with bridging plate osteosynthesis versus conservative treatment with functional brace for humeral shaft fractures in adult men and women for better functional results and quality of life: a randomised controlled trial

Study objectives

Surgical intervention with bridging plate osteosynthesis for humeral shaft fractures leads to better functional results with better quality of life and earlier return to previous activities compared to conservative treatment with functional brace.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Universidade Federal de Sao Paulo approved on the 5th February 2010 (ref: 1595/09)

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Humeral shaft fracture

Interventions

Bridging plate osteosynthesis versus treatment with functional brace. Total duration of follow-up: 2 years.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Disability Arm Shoulder and Hand questionnaire (DASH)
2. Time to return to previous activities

All outcomes will be assessed at 1, 2, 4, 8, 16, 24, 48, 96 weeks.

Key secondary outcome(s)

1. Pain on Visual Analogue Scale (VAS)
2. Radiologic assessment
3. Treatment cost
4. Rate of secondary surgery
5. Rate of complications
6. Social impact on 36-item short form health survey (SF-36)

All outcomes will be assessed at 1, 2, 4, 8, 16, 24, 48, 96 weeks.

Completion date

31/12/2012

Eligibility

Key inclusion criteria

1. Men or women greater than or equal to 18 years old
2. Deviated humeral shaft fracture
3. Trauma-surgery delay of less than 21 days
4. Consent form signed

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Pathological fractures
2. Open humeral fractures
3. Associated vascular injury
4. Associated nerve injury
5. Inability to comply with rehabilitation or form completion
6. Likely problems, in the judgement of the investigators, with maintaining follow-up (i.e. patients with no fixed address, patients not mentally competent to give consent, etc.)
7. Any situation that contra-indicate any of the methods to be randomised

Date of first enrolment

15/07/2010

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

Brazil

Study participating centre

Rua Borges Lagoa

Sao Paulo

Brazil
04038042

Sponsor information

Organisation

Federal University of Sao Paulo (Brazil)

ROR

<https://ror.org/02k5swt12>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospital Sao Paulo (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/08/2013		Yes	No