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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered	
18/05/2010		[X] Protocol	
Registration date	Overall study status	Statistical analysis plan	
16/06/2010	Completed	☐ Results	
Last Edited	Condition category	Individual participant data	
09/08/2013	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

Contact name

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Contact details

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Additional identifiers

Protocol serial number N/A

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 questionnare (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

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
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes