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

Submission date	Recruitment status	[X] Prospectively registered
18/05/2010	No longer recruiting	[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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 measure
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.

Secondary outcome measures
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.

Overall study start date
15/07/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
126

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)

Sponsor details
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Sponsor type
University/education

Website
http://www.unifesp.br

ROR
https://ror.org/02k5swt12

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital Sao Paulo (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

Study outputs

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