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Treatment of reducible unstable fractures of the distal extremity of the radius: external fixation versus percutaneous pinning

Submission date	Recruitment status	[_] Prospectively registered
22/10/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/12/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/02/2011	Injury, Occupational Diseases, Poisoning	

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 reducible unstable fractures of the distal extremity of the radius: external fixation versus percutaneous pinning - a randomised clinical trial

Study objectives
The aim of this study was to test the hypothesis that the modified DePalma method for percutaneous pinning would produce anatomical and functional results similar to those of external joint fixation in the treatment of unstable reducible intra or extra-articular fractures of the distal extremity of the radius in adult patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Federal University of Sao Paulo (Universidade Federal de Sao Paulo) approved on the 9th August 2002 (ref: 0582/02)

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
Colles' fracture

Interventions
Transulnar percutaneous pinning (De Palma) versus bridging external fixation. The total duration of follow-up was 2 years.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Measured at 6 months and 2 years:
1. Disability Arm Shoulder and Hand questionare (DASH)
2. Visual Analogue Scale (VAS)

Secondary outcome measures
Measured at 6 months and 2 years:
1. Radiographic outcomes: radiographs in posteroanterior and lateral views were used for evaluation, and the following parameters were measured: volar inclination angle, radial inclination angle, presence of a stepped joint and consolidation.
2. Objective functional assessment: range of motion and grip
3. Complications and failures

Functional and radiographic evaluations, pain measurements using the VAS, and applications of the DASH questionnaire were performed by professional orthopedists and physiotherapists who were not directly associated with the study

Overall study start date
01/03/2002

Completion date
30/06/2004

Eligibility

Key inclusion criteria
The patients were adults aged over 40 years (either sex) who presented with acute fractures with displacement up to 10 days old without previous treatment. The fractures were categorised using the Cooney classification 10 as unstable and reducible: type IIb and type IVb. Fractures were considered unstable if they presented three or more of the following factors at the initial radiographic examination:
1. Shortening of the radius by more than 5 mm
2. Dorsal angulation greater than 20 degrees
3. Joint incongruence
4. Fracture associated with the styloid process of the ulna
5. Dorsal comminution of the metaphysis
6. Aged greater than 60 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Fractures with volar angulation (Smith fracture)
2. Joint margin fractures (Barton fracture)
3. Open or bilateral fractures
4. Fractures that could not be reduced
5. Patients with previous histories of degenerative disease, wrist joint trauma, or traumatic injuries associated with the fracture that would make it impossible to apply the proposed surgical methods or evaluate the results
6. Patients who refused to sign the free and informed consent statement

Date of first enrolment
01/03/2002

Date of final enrolment
30/06/2004

Locations

Countries of recruitment
Brazil

Study participating centre
Federal University of Sao Paulo
Sao Paulo
Brazil
04038042

Sponsor information

Organisation
Federal University of Sao Paulo (Brazil)

Sponsor details
Rua Borges Lagoa
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Sao Paulo
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04038042

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?
Results article	results	29/06/2010		Yes	No