

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

Submission date
22/10/2009

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
02/12/2009

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
09/02/2011

Condition category
Injury, Occupational Diseases, Poisoning

Individual participant data

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

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

Study type(s)

Treatment

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(s)

Measured at 6 months and 2 years:

1. Disability Arm Shoulder and Hand questionnaire (DASH)
2. Visual Analogue Scale (VAS)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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?
Results article	results	29/06/2010		Yes	No