

External fixation or volar plating for treating deviated distal radius fracture

Submission date 27/05/2011	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 14/06/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 03/11/2014	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
External fixation or volar plating for treating deviated distal radius fracture: randomized clinical trial

Study objectives
Osteosynthesis with volar blocked plate has functional, anatomic results, failure and complication rate similar to the treatment with external fixation method

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Federal University of São Paulo, São Paulo, Brazil (Comitê de ética em pesquisa da Universidade Federal de São Paulo) ref: 0011-11, January 2011

Primary study design

Interventional

Study design

Randomized clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Deviated distal radius fracture

Interventions

1. The patients will be allocated in two treatment options, regarding to operative treatment of distal radius fracture:

1.1. Volar plating, which consists of an open reduction and internal fixation using a volar plate

1.2. External fixation which consist of a transarticular bridging fixation. All the patients will be followed at 1, 3, 6, 9, 12 weeks and 6, 12 months.

2. All patients will be followed by the research team for 1 year

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Functional assessment

2. Patient satisfaction with the surgical method

3. All outcomes (DASH, SF-36, VAS) will be applied at 3, 6, 12 weeks and 6 and 12 months

Key secondary outcome(s)

1. Anatomic and radiographic

2. Complications

3. Method failure

Completion date

01/03/2014

Eligibility

Key inclusion criteria

1. Adult patients of both genders

2. Acute fractures (up to 15 days) in the distal edge of the radius, reducible and unstable, who

have not been submitted to previous surgical treatments.

3. Palmar blocked plate or with external fixation method for treating desviated distal radius fracture

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients with marginal or irreducible fractures
2. Previous history of degenerative or traumatic pathology in the articulation of the wounded or contralateral wrist
3. Bilateral fracture, exposed fractures, with tendinous or neurovascular injuries
4. Patients with systemic diseases or traumatic injuries associated with the fracture, which restrict application of the methods or assessment of the results
5. Refusal to the consent term

Date of first enrolment

01/03/2012

Date of final enrolment

01/03/2014

Locations

Countries of recruitment

Brazil

Study participating centre

Rua Borge Lagoa nº 778 Vila Clementino

São Paulo

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Sponsor information

Organisation

Federal University of São Paulo (Brazil)

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

Foundation for Research Support of São Paulo (Fundação de amparo à pesquisa do estado de São Paulo - FAPESP)

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	05/03/2014		Yes	No