

# External fixation or volar plating for treating deviated distal radius fracture

<b>Submission date</b> 27/05/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 14/06/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/11/2014	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## 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

### **Study design**

Randomized clinical 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**

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 measure**

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

**Secondary outcome measures**

1. Anatomic and radiographic
2. Complications
3. Method failure

**Overall study start date**

01/03/2012

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

36 patients in each group

**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

Brazil

04038-032

## Sponsor information

### Organisation

Federal University of São Paulo (Brazil)

### Sponsor details

c/o Dr Jorge Raduan Neto

Rua Borges Lagoa nº 778

São Paulo

Brazil

04038-032

### Sponsor type

University/education

### 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

## 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?
<a href="#">Results article</a>	results	05/03/2014		Yes	No