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External fixation or volar plating for treating deviated distal radius fracture

Submission date	Recruitment status
27/05/2011	No longer recruiting
Registration date	**Overall study status**
14/06/2011	Completed
Last Edited	**Condition category**
03/11/2014	Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
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 Univeristy of São Paulo, São Paulo, Brazil (Comitê de ética em pesquisa da Universidade Federal de Sâo Paulo) ref: 0011-11, January 2011

Study design
Randomized clinical trial

Primary study design
Interventional

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 platting, 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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04038-032

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 pesquesa do esado 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