# Reduction of acute anterior shoulder dislocation with or without the use of articular lidocaine anaesthesia

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
03/04/2011		[] Protocol		
Registration date	Overall study status	Statistical analysis plan		
26/04/2011	Completed	[X] Results		
Last Edited 27/09/2013	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	Individual participant data		

### Plain English summary of protocol

Not provided at time of registration

## **Contact information**

**Type(s)** Scientific

**Contact name** Dr Marcel Tamaoki

#### **Contact details**

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# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers N/A

# Study information

#### Scientific Title

Reduction of acute anterior shoulder dislocation with or without the use of articular lidocaine anaesthesia: a prospective randomised controlled trial

#### **Study objectives**

The intra-articular lidocaine could reduce pain for treatment of shoulder dislocation.

**Ethics approval required** Old ethics approval format

#### Ethics approval(s)

Hospital Sao Paulo Research Ethics Committee (Cpmitê de Ética em Pesquisa Hospital São Paulo) approved on 08/08/2008 (ref: CEP 1019/08)

#### Study design

Prospective 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

Anterior shoulder dislocation

#### Interventions

After fulfilling the study inclusion and exclusion criteria, each patient received a sequential registration number and a sealed, opaque envelope marked with the number corresponding to their registration. The envelope contained information regarding the treatment method that was randomly assigned to the patients registration number. The attending physician led the patient to a waiting room where after the door was closed and the envelope was opened, either intra-articular lidocaine injection was applied or no treatment was given in accordance to the method disclosed. In both cases, the anatomical region of the arm corresponding to the application of intra-articular anaesthetic was covered with dressings to mask whether or not the intervention had been performed. Whether or not the patients underwent the intervention, all patients were placed supine on a stretcher with the affected shoulder at 60° abduction. The pull maneuver and counter-traction were performed with a bedsheet placed under their armpit.

#### Intervention Type

Drug

**Phase** Not Applicable

#### Drug/device/biological/vaccine name(s)

Lidocaine

#### Primary outcome measure

Pain was assessed through the application of a visual analogue scale at the time of pre reduction, and 1 and 5 minutes after the reduction maneuver was performed

#### Secondary outcome measures

- 1. The time span to achieve shoulder joint reduction in minutes
- 2. Neurological, vascular and infectious complications

3. Occurrence of failures were also assessed (defined as unsuccessful reduction after a 10minute attempt). After 5 minutes, two other physicians were called to perform the reduction maneuver. Both were blinded to which treatment the patient had received.

#### Overall study start date

01/09/2008

#### **Completion date**

31/12/2009

# Eligibility

#### Key inclusion criteria

All patients with acute anterior shoulder dislocation who were treated at the Emergency Room of Hospital Sao Paulo were included in the study.

The diagnostic criteria used were clinical findings:

1. Shoulder deformity

2. Acute pain and disability for active and passive mobility of the shoulder

3. Radiographic findings showing total loss of articular congruity between the humeral head and glenoid cavity, as evidenced by frontal, profile and axillary shoulder radiographs

#### Participant type(s)

Patient

Age group

Adult

**Sex** Both

# **Target number of participants** 40

Key exclusion criteria

1. Patients who were diagnosed with fracture-dislocation of the shoulder joint, except those with Hill-Sachs lesions, were disqualified

2. Patients with immature skeletons (open physis), who underwent surgery, or had previous fractures in the affected shoulder

3. Patients in whom the use of lidocaine is contraindicated

4. Those who refused to sign the consent form

#### Date of first enrolment

01/09/2008

## Date of final enrolment

31/12/2009

## Locations

**Countries of recruitment** Brazil

**Study participating centre Rua das Rosas 126 apto 73** São Paulo Brazil 04048-000

## Sponsor information

**Organisation** Federal University of Sao Paulo (Universidade Federal de São Paulo) (Brazil)

#### Sponsor details

Disciplina de Mão e Membro Superior Rua Borges Lagoa 786 São Paulo Brazil 04023-900 tamaoki@unifesp.br

## Sponsor type

University/education

#### 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?
<u>Results article</u>	results	01/10/2012		Yes	No