ISRCTN27127703 https://doi.org/10.1186/ISRCTN27127703

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

Submission date
03/04/2011

Recruitment status
No longer recruiting

Registration date
26/04/2011

Overall study status
Completed

Last Edited
27/09/2013

Condition category
Injury, Occupational Diseases, Poisoning

[ ] 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

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 10-minute 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)

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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?
Results article	results	01/10/2012		Yes	No