

The effectiveness of a specially designed shoulder chair for closed reduction of acute shoulder dislocation in the emergency department

Submission date 22/05/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/07/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/10/2012	Condition category Signs and Symptoms	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

Flat C, 2/F, Block 22, Phase 3

Classical Gardens

Tai Po

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China

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Additional identifiers

Protocol serial number

CRE-2008.326-T

Study information

Scientific Title

The effectiveness of a specially designed shoulder chair for closed reduction of acute shoulder dislocation in the emergency department: a prospective, unblinded randomised controlled trial

Study objectives

The aim of this study is to demonstrate the effectiveness of the new reduction method by measuring:

1. Length of patient accident and emergency (A & E) stay
2. Length of the procedure
3. Successful reduction rate
4. Levels of pain experienced by patients in different time periods before and after the reduction

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Joint Chinese University of Hong Kong (CUHK) and New Territories East Cluster (NTEC) Clinical Research Ethics Committee gave approval on the 13th October 2008 (ref: CRE-2008.326-T)

Primary study design

Interventional

Study design

Prospective unblinded randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute shoulder dislocation

Interventions

Subjects will be randomly assigned into two study groups. In the normal practice group, the Kocher's manoeuvre will be suggested as a primary reduction technique. Emergency physicians can also use any recognised method for closed reduction according to their preferences and clinical judgment. Physicians should follow the pre-established study analgesic and sedation pathway to give medication. In the shoulder chair group, shoulder reduction will be performed by emergency physicians or emergency nurse practitioners.

Oral medication:

In both groups, oral paracetamol 1 g will be used.

Intravenous medication:

Both groups can have rescue analgesia - intravenous morphine 2 mg (increments as required) if patient requests.

In addition, for the normal practice group, intravenous 2 mg of midazolam will be used before conducting the reduction. Physicians can titrate 1 mg every 2 - 3 minutes to improve conditions to allow a satisfactory level of sedation for reduction.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Length of patient stay in the ED, measured one and half years after the study commenced.

Key secondary outcome(s)

1. Length of the procedure
2. Successful reduction rate
3. Levels of pain experienced by patients in different time periods before and after the reduction

Measured one and half years after the study commenced.

Completion date

31/07/2010

Eligibility

Key inclusion criteria

Sample criteria are non-exclusive to gender and ethnic background. The sample inclusion criteria consists of:

1. Aged greater than or equal to 18 years
2. Anterior or posterior shoulder dislocation without fracture of the surgical neck of humerus
3. Patient who is able to communicate and cooperate
4. Height 150 cm or above

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Acute psychiatric disease
2. Inability to complete assessment of pain, e.g. dementia
3. Contraindications to any study medication

Date of first enrolment

01/07/2009

Date of final enrolment

31/07/2010

Locations

Countries of recruitment

China

Hong Kong

Study participating centre

Flat C, 2/F, Block 22, Phase 3

Hong Kong

China

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Sponsor information

Organisation

The Hong Kong College of Emergency Medicine (China)

Funder(s)

Funder type

University/education

Funder Name

The Hong Kong College of Emergency Medicine (China) - Research Grant

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details results	Date created	Date added	Peer reviewed?	Patient-facing?
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[Results article](#)

01/10/2013

Yes

No