ISRCTN49254586 https://doi.org/10.1186/ISRCTN49254586

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/07/2009	**Overall study status** Completed	
Last Edited 29/10/2012	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Josephine Yuen Man Chung

Contact details
Flat C, 2/F, Block 22, Phase 3
Classical Gardens
Tai Po
Hong Kong
China
-

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

Study design
Prospective unblinded 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
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 measure
Length of patient stay in the ED, measured one and half years after the study commenced.

Secondary outcome measures
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.

Overall study start date
01/07/2009

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

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30 patients in each of two groups (total = 60)

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
-

Sponsor information

Organisation
The Hong Kong College of Emergency Medicine (China)

Sponsor details
Room 809 HKAM Jockey Club Building
99 Wong Chuk Hang Road
Aberdeen
Hong Kong

China
-

Sponsor type
University/education

Website
http://www.hkam.org.hk/colleges/em.htm

Funder(s)

Funder type
University/education

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

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	01/10/2013		Yes	No