BRASD: Biomechanical Reposition techniques in Anterior Shoulder Dislocation. A randomised multicenter clinical trial.

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Which BRT or combination of BRT is the fastest, least painful, has the lowest complication rate and gives the highest patient satisfaction for adult patients with an anterior shoulder dislocation presenting in the emergency department?

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON47421

Source
ToetsingOnline

Brief title
BRASD-trial

Condition

- Bone and joint therapeutic procedures

Synonym
Shoulderdislocation

Research involving
Human

Sponsors and support

Primary sponsor: Flevoziekenhuis

Source(s) of monetary or material Support: vakgroepen SEH

Intervention

Keyword: repositiontechniques, schoulderdislocation

Outcome measures

Primary outcome

- length of ED stay in minutes, defined as the moment of arrival at the ED

until the patient is discharged

- levels of pain experienced by patient before, during and after reduction,

measured by NRS (Numeric rating scale (0-10)

Secondary outcome

- Time needed for reduction in minutes from start until end of reduction

- Numbers of techniques used for reduction

- Use of analgesia and/or sedatives (which and dosage), pre-hospital and/or in

hospital administered

- Pre-reduction status of osseous (x-ray) and neurovascular (physical exam) of

the shoulder

- Iatrogenic complications (osseous or neurovascular)

- Age, gender, ASA classification, last meal (2,4,6 hours, type of meal)

- First episode or recurrent dislocation

- Trauma mechanism

Study description

Background summary

Shoulder dislocations are one of the most common dislocations in an emergency department (ED). Shoulder dislocations are very painful and need direct intervention to minimize discomfort and potential tissue damage (cartilage, nerve and vascular). Reposition techniques are divided in three groups: traction based (e.g. Hippocrates), leverage (e.g. Kocher) or biomechanical techniques (e.g. Cunningham). Common practice are traction or leverage based techniques which have proven to be successful in shoulder repositioning. However, these techniques do not meet the requirements of quick, painless or complication less reposition. They do not focus on patient satisfaction and the prevention of emergency department crowding. Because of these limitations we have looked in the literature for other techniques and based this search we have found that biomechanical reposition techniques (BRT) do fulfil these requirements. However it is not clear from the literature what the fastest or least painful BRT or combination of BRT is.

Study objective

Which BRT or combination of BRT is the fastest, least painful, has the lowest complication rate and gives the highest patient satisfaction for adult patients with an anterior shoulder dislocation presenting in the emergency department?

Study design

A randomized multicenter trial.

Intervention

Depending on ability to adduct subjects will be randomized for biomechanical repositioning according to Cunningham, Modified Milch or Scapular manipulation technique and Modified Milch or Scapula manipulation technique.

Study burden and risks

All non-biomechanical techniques are based on traction or leverage and are therefore inherently painful and potentially harmful. The biomechanical techniques used in this study are more physiological and are less painful. No adverse events are described in the biomechanical reduction techniques.If the biomechanical reduction techniques fail and the treating physician will subsequently use another technique, more time will be needed for reduction. In that case procedure time will not differ compared to a traction or leverage based technique because of the usual set up time for sedation, analgesia and monitoring used with the traditional techniques.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

all, legally competent, adult subjects (*18 years) with an isolated anterior shoulder dislocation

Exclusion criteria

- subcapital humeral fractures
- multi trauma
- subclavicula-, thoracic- , inferior or posterior dislocation
- dislocations presented after 24 hours.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-08-2016
Enrollment:	222
Type:	Actual

Ethics review

Approved WMO Date:	04-07-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20640
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL54173.094.15
OMON	NL-OMON20640