

Reduction of the anterior shoulder dislocation with three different methods

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		<input type="checkbox"/> Protocol
Registration date 27/02/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 27/02/2009	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Study information

Scientific Title
The new FARES (FAst REliable Safe) method of reduction of the acute anterior dislocation of the shoulder: a prospective randomised comparative study

Study objectives
Anterior dislocations of the glenohumeral joint are very common. This is probably the result of the shoulder anatomy that predisposes to instability. There are several methods of reduction of

the anterior dislocation of the shoulder, including those introduced by Hippocrates, Kocher Milch and Stimpson; rates of success and complications following reduction range according to the method used. Although most anterior shoulder dislocations can be easily reduced at the Accident and Emergency Departments (AE) of most hospitals, some dislocations will still require the implementation of more than one method(s) and in 5% to 10% of cases, reduction can only be achieved at an operating theatre.

The optimal method of reduction should require minimal assistance to the physician performing it and it ought to be highly effective, quick, safe and painless. Choosing which method to use is a whole different issue, since most physicians seldom base their decision on objective criteria. This however is more or less expected since there are only a few studies in the literature that compare the efficacy, safety and reliability among different techniques and most of them are lacking comparison groups, blinded methodology, or proper statistical analysis.

This trial compares the efficacy of the FARES (FAst RELiable Safe) method, a new method to reduce shoulder dislocation, against two traditional methods ("Hippocrates" and "Kocher" methods).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Scientific and Ethical Committee, Papageorgiou General Hospital of Thessaloniki, approved on 29/09/2008.

Study design

Prospective parallel-group randomised controlled single-centre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Traumatic shoulder dislocation

Interventions

Participants were randomly allocated to the following three arms:

1. The FARES method
2. The "Hippocrates" method
3. The "Kocher" method

Duration of treatment for each participant was up to 10 min in all arms.

All trial outcomes were assessed immediately after the treatment (no follow-up assessments).

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Efficacy of each individual method as far as the reduction of the shoulder dislocation was concerned. The efficacy was validated by x-rays following the reduction attempt and by the ability of the patient to perform voluntary and painless movements of the affected arm.

Key secondary outcome(s)

1. Evaluation of the pain felt during the reduction, measured using the Visual Analogue Scale (VAS) score (0 = no pain, 10 = unbearable pain)
2. Evaluation of the existence of any immediate complication following the reduction of the shoulder dislocation

Completion date

01/06/2008

Eligibility

Key inclusion criteria

1. Adults (>18 years old), both males and females
2. Patients suffering from 'first-time' traumatic anterior dislocation of the shoulder (either accompanied by a fracture of the greater humeral tuberosity or not)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Patients suffering from voluntary and/or recurrent dislocation or reporting prior episode(s) of subluxation
2. Patients suffering from dislocation associated with 3- or 4-parts fracture of the proximal humerus
3. Patients with duration of dislocation greater than 24 hours
4. Intoxicated patients
5. Patients that had used any analgesics and/or muscle relaxants before attempting reduction

Date of first enrolment

01/09/2006

Date of final enrolment

01/06/2008

Locations

Countries of recruitment

Greece

Study participating centre

Third Orthopaedic Department

Thessaloniki

Greece

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Sponsor information

Organisation

Aristotle University of Thessaloniki (Greece)

ROR

<https://ror.org/02j61yw88>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Aristotle University of Thessaloniki Medical School, Papageorgiou General Hospital, Third Orthopaedic Department (Greece)

Results and Publications

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

Not provided at time of registration