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Reduction of the anterior shoulder dislocation with three different methods

Submission date	Recruitment status	[ ] Prospectively registered
28/01/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/02/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/02/2009	Musculoskeletal Diseases	[ ] 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

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
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 measure
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.

Secondary outcome measures
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

Overall study start date
01/09/2006

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

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
144

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
546 03

Sponsor information

Organisation
Aristotle University of Thessaloniki (Greece)

Sponsor details
Medical School
Bio-Ethics Committee

University Campus
Thessaloniki
Greece
541 24

Sponsor type
University/education

Website
http://www.med.auth.gr

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

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