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Diagnostic accuracy of Point of Care Ultrasound (PoCUS) for shoulder dislocations and reductions in the emergency department – a diagnostic randomised control trial

Submission date
27/09/2019

Recruitment status
No longer recruiting

Registration date
30/09/2019

Overall study status
Completed

Last Edited
14/04/2020

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The purpose of this study is to determine whether ultrasound improves diagnostic accuracy when used with physical examination for confirmation of shoulder dislocation and for confirmation of shoulder reduction. The current practice involves physical examination and X-rays (that rely on harmful ionising radiation) to evaluate for any dislocations and/or fractures of the shoulder and upper arm. X-rays will be used as the gold standard investigation for this study.

Who can participate?
All adult patients presenting to the Emergency Department of Mater Dei Hospital in Malta, with acute trauma to the shoulder will be eligible to take part in the study.

What does the study involve?
A number of emergency doctors will be trained to do an ultrasound investigation to check specifically for shoulder dislocation and an upper arm fracture. Patients who fit the inclusion criteria for this study will be asked for consent to take part in this study. They will also be randomised to one of two groups. The control group is the standard physical examination alone and the experimental group which involves adding ultrasound to the physical examination. All patients will have X-rays done as per standard protocol irrespective of which group they are randomised to. Those patients who have a shoulder dislocation will need reduction as per the standard procedure. These patients will have a second examination following reduction. This examination will be either a physical exam or ultrasound exam, depending on which group patients were randomised to initially. All Emergency doctors taking part in this study are advanced trainees or specialists in emergency medicine with training in Level 1 ultrasound as a minimum. All X-rays will be reported by board-certified radiologists.

What are the possible benefits and risks of participating?
No painful, time consuming or irradiating interventions will be added on to participants. The participants themselves may benefit from the conclusions of the study. Benefits for future

treatments may include a decreased radiation dose and exposure, a shorter time in the ED, confirmation of shoulder reduction at bedside (thus avoiding unnecessary re-sedation) and fewer costs.

Where is the study run from?
Mater Dei Hospital Emergency Department, Malta

When is the study starting and how long is it expected to run for?
October 2019 to March 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
FRECMDS_1819_036

Study information

Scientific Title

In adult patients (age >16yrs) presenting to the ED with acute traumatic shoulder pain, can PoCUS improve diagnostic accuracy for shoulder dislocation with or without proximal humeral fractures and shoulder reduction when combined to physical examination as opposed to physical examination alone?

Study objectives
H0: The null hypothesis for this study will be that there is no difference in diagnostic accuracy between physical examination with PoCUS and physical examination alone using X-rays as the gold standard.
H1: The unidirectional experimental hypothesis, however, will be that diagnostic accuracy will be significantly higher when using point of care ultrasound with physical examination.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 27/03/2019, Faculty Research Ethics Committee of Medicine and Surgery University of Malta (Faculty of Health Sciences, Mater Dei Hospital, Msida, Malta, MSD 2080; +356 23401830; healthsciences@um.edu.mt), ref: FRECMDS_1819_036
2. Approved 07/09/2019, Research Ethics Sub-Committee School of Health and Social Care Teesside University (Teesside University, Middlesbrough, Tees Valley, TS1 3BX, UK; +44 (0)1642 21812; SOHSC-Ethics@tees.ac.uk), ref: 281/18

Study design
Single-centre quantitative open parallel randomised control study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Shoulder dislocations with or without proximal humeral fractures

Interventions
Consecutive patients presenting to Mater Dei Hospital ED, with acute traumatic shoulder pain will be eligible to take part in the study. Eligible patients will be accompanied to a predefined room and adequate analgesia will be administered. Consent will be obtained from the patient.

Patients will be randomised to either the control (physical examination only) or experimental group (physical examination and POCUS), by opening a sealed envelope. These envelopes will be prepared before the start of the study and will contain computer generated random allocations.

The investigator will then proceed to perform either the clinical examination or the clinical examination with PoCUS. Patients will then proceed to X-rays (gold standard) as per usual protocol to confirm diagnosis.

After completion of X-rays, patients will either proceed to have a shoulder dislocation reduction or other treatment if reduction is deemed inappropriate or not necessary by the investigator. After reduction, another examination will be conducted (depending on which limb patient was randomised) to ascertain successful reduction. Investigators will record findings on a data collection sheet before any X-rays to minimise review bias. All X-rays will be reported by the attending radiologists who are blinded to the investigator's results to avoid diagnostic review bias.

Intervention Type
Other

Primary outcome measure
Success rate of clinical examination or the clinical examination with PoCUS at detecting the presence or absence of shoulder dislocation with or without proximal humeral fracture and the presence or absence of successful shoulder reduction

Secondary outcome measures
None

Overall study start date
01/01/2019

Completion date
31/03/2020

Eligibility

Key inclusion criteria
1. Over 16 years old
2. Acute shoulder pain and decreased range of motion post-trauma
3. Patient able to give informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

500

Total final enrolment
1206

Key exclusion criteria
1. Chronic shoulder pain
2. Poly-trauma patients needing emergency surgery like laparotomy
3. Patients referred with a confirmed diagnosis of shoulder dislocations on X-ray

Date of first enrolment
01/10/2019

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
Malta

Study participating centre
Mater Dei Hospital Emergency Department
Triq Dun Karm
Msida
Malta
MSD2090

Sponsor information

Organisation
Faculty of Medicine and Surgery University of Malta Malta Medical School

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Block A
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Sponsor type

Hospital/treatment centre

Website
http://www.um.edu.mt

ROR
https://ror.org/03a62bv60

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Results will be published in a medical journal once analysis is completed.

Intention to publish date
01/09/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality

IPD sharing plan summary
Not expected to be made available