Acute rehabilitation following traumatic anterior shoulder dislocation

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
03/09/2018		[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
07/09/2018		[X] Results		
Last Edited 18/01/2024	Condition category Injury, Occupational Diseases, Poisoning	Individual participant data		
10/01/2024	injury, occupacional diseases, Poisoning			

Plain English summary of protocol

Current plain English summary as of 24/03/2022:

Background and study aims

Shoulder dislocations occur when the upper end of the arm bone is forced out of its joint socket because of a traumatic event. It is common and results in pain, disability and decreased function. Currently in the UK, some hospitals offer a single session of advice and some offer a course of physiotherapy. The UK guidelines currently say a course of physiotherapy 'may be helpful', whilst other national guidelines say advice alone is needed. The aim of this study is to compare a single session of advice versus a course of physiotherapy for patients who have dislocated their shoulder.

Who can participate?

Patients aged 18 or over with a dislocated shoulder managed without an operation

What does the study involve?

Participants are randomly allocated to either a single session of advice or the same session followed by a course of physiotherapy. Both treatments are widely used, and clinical teams across the UK are familiar with both. The two treatment groups are compared for differences in shoulder function at 6 months after the injury. Improvements in function and quality of life as well as complications and resource use are also measured at 6 weeks, 3, 6, and 12 months later.

What are the possible benefits and risks of participating?

Both treatments are widely used for people with a dislocated shoulder. There is no specific advantage to participants. This study may, however, improve the treatment of patients with shoulder dislocations in the future. There are minimal risks involved with this study. Both advice alone and advice in addition to tailored physiotherapy are current practice across the NHS for the management of a dislocated shoulder. Consequently, both treatments reflect current standard practice and do not involve any substantial risks over and above standard care currently received. In order to minimise burden to patients, the completion of all follow-up questionnaires may be done at home so patients will not have to make additional trips to the hospital. Postal questionnaires will include a free post envelope to make the return of questionnaires as easy as possible.

Where is the study run from?

University Hospitals Coventry and Warwickshire (lead centre) and 49 other sites in the UK.

When is the study starting and how long is it expected to run for? March 2018 to November 2022

Who is funding the study? National Institute for Health Research (NIHR) (UK)

Who is the main contact? Helen Bradley/Anish Patel artisan@warwick.ac.uk

Previous plain English summary:

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Where is the study run from?

- 1. Leicester Royal Infirmary
- 2. Royal Devon and Exeter Hospital
- 3. Southmead Hospital
- 4. University Hospitals Coventry and Warwickshire (lead centre)
- 5. University Hospital of North Tees and Hartlepool
- 6. Norfolk and Norwich University Hospital

- 7. Addenbrooke's Hospital
- 8. Royal Free London Hospital
- 9. Royal Derby Hospital
- 10. Yeovil District Hospital
- 11. Royal Victoria Infirmary
- 12. Harrogate District Hospital

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Who is the main contact? Helen Bradley/Anish Patel artisan@warwick.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Helen Bradley

Contact details

Warwick Clinical Trials Unit Clinical Sciences Research Laboratories University Hospitals Coventry and Warwickshire Coventry United Kingdom CV2 2DX +44 (0)2476968624 artisan@warwick.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 39168

Study information

Scientific Title

Acute rehabilitation following traumatic anterior shoulder dislocation

Acronym

ARTISAN

Study objectives

Shoulder dislocations occur when the upper end of the arm bone is forced out of its joint socket because of a traumatic event. It is common and results in pain, disability and decreased function. Currently in the UK, some hospitals offer a single session of advice and some offer a course of physiotherapy. The UK guidelines currently say a course of physiotherapy 'may be helpful'; whilst other national guidelines say advice alone is needed. The trialists plan to perform a study across 30 UK hospitals to compare a single session of advice versus a course of physiotherapy for patients who have dislocated their shoulder. The primary aim is to compare the two treatment groups for differences in the Oxford Shoulder Instability Score six months after injury. This score measures function from the patients' perspective. Improvements in functional outcome and quality of life as well as complications and resource use will be collected at 6 weeks, 3, 6 and 12 months after taking part in the study.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Gwasanaeth Moeseg Ymchwil Research Ethics Committee, 26/07/2018, ref: 18/WA/0236

Study design

Randomized; Interventional; Design type: Treatment, Education or Self-Management, Rehabilitation

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Shoulder dislocation

Interventions

Participants deemed eligible to take part in the trial, according to the protocol will be approached to be invited to the study. After time to consider, written informed consent will be obtained. Participants will be asked to complete three questionnaires at baseline; Oxford Shoulder Instability Score (OSIS), QuickDASH, and EQ5D-5L. Referral to a physiotherapist will be made at this stage. Eligibility will then be re-checked and participants will be requested to complete post injury questionnaires and receive single-session of advice from Physiotherapist. Participants will then be randomised to continue advice only following discharge from physiotherapy or receive further physiotherapy for a minimum of two sessions over a maximum of four months post randomisation. Participants will be aware of which treatment arm they have been randomised to as it's an open label trial. Participants will be required to complete postal questionnaires at 6 weeks, 3, 6 and 12 months following randomisation to indicate their typical pre-injury and current health status. Completed questionnaires are to be posted back to the trials unit using free post envelopes provided. Some participants will also be invited to take part in a qualitative interview.

Intervention Type

Other

Primary outcome(s)

Oxford Shoulder Instability Score (OSIS): The OSIS is a self-completed outcome measure containing 12 questions (0-4 points each), with possible scores from 0 (best function) to 48 (worst function) (8, 11). These questions relate to activities of daily living particularly relevant to patients exhibiting shoulder instability. The OSIS has been specifically designed to assess outcome of therapy (both surgical and non-surgical) by measuring activities of daily living and pain of patients exhibiting shoulder instability. Measured at 6 months after injury.

Key secondary outcome(s))

Measured at 6 weeks, 3, 6 and 12 months after taking part in the study:

- 1. QuickDASH: The QuickDASH is a self-completed shortened version of the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire. Instead of 30 items, the QuickDASH uses 11 items to measure physical function and symptoms in people with any or multiple musculoskeletal disorders of the upper limb. The questionnaire was designed to help describe the disability experienced by people with upper-limb disorders and also to monitor changes in symptoms and function over time
- 2. EQ-5D-5L: Is a well validated, generic health-related quality of life measure consisting of five dimensions each with 5-levels of response. Each combination of answers can be converted into a health utility score. It has good test-retest reliability, is simple for participants to use, and gives a single preference based index value for health status that can be used for broader cost-effectiveness comparative purposes
- 3. Complications: Complications will be reported through the following mechanisms: a) Participant reported during routine collection of follow up data; b) Local research teams will report any additional investigations or treatment of participants c) Local physiotherapists delivering the trial interventions will report any events occurring during treatment sessions d) Medical records of non-responding participants may be retrieved by local research teams at site. Complications will be defined into three categories: a) Pre-defined complications directly related to the trial interventions b) Pre-defined complications directly caused by the primary TASD event not identified by the initial assessing clinician, but subsequently identified c) Complications not related to the intervention or TASD event and will subsequently not be formally analysed or reported
- 4. Resource use questionnaires: The primary health-economic analysis will concentrate on direct intervention and healthcare/personal social services costs, while wider impact (societal) costs will be included within the sensitivity analyses. Participants will complete resource use questionnaires at baseline and all follow-up points, to collect resource use data associated with the interventions under examination. The trialists will use techniques common in long-term cohort studies to ensure minimum loss to follow-up, such as collection of multiple contact addresses and telephone numbers, mobile telephone numbers and email addresses. The trial team may keep in regular contact with participants using newsletters

Completion date 30/11/2022

Eligibility

Key inclusion criteria

- 1. Provision of written informed consent
- 2. Aged 18 years or over
- 3. Patients have a primary traumatic acute shoulder dislocation, confirmed by radiology

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

482

Key exclusion criteria

- 1. Bilateral shoulder dislocation
- 2. Having first-line surgical treatment (Indications include a displaced greater tuberosity fracture for example)
- 3. Cannot receive first session of physiotherapy within 6 weeks of injury
- 4. In the opinion of the assessing clinician there is a neurovascular complication associated with TASD
- 5. Unable to adhere to trial procedures or complete questionnaires; for example, a history of permanent cognitive impairment
- 6. Previous randomisation in the present trial

Date of first enrolment

01/11/2018

Date of final enrolment

14/03/2022

Locations

Countries of recruitment

United Kingdom

England

Scotland

Wales

Study participating centre Leicester Royal Infirmary

Infirmary Square Leicester United Kingdom LE1 5WW

Study participating centre Royal Devon and Exeter Hospital

Barrack Road Leicester United Kingdom EX2 5DW

Study participating centre Southmead Hospital

Southmead Road Bristol United Kingdom BS10 5NB

Study participating centre University Hospitals Coventry and Warwickshire (lead centre)

Clifford Bridge Road Coventry United Kingdom CV2 2DX

Study participating centre University Hospital of North Tees and Hartlepool

Hardwick Road Hardwick Stockton-on-Tees United Kingdom TS19 8PE

Study participating centre Norfolk and Norwich University Hospital

Colney Lane

Colney Colney United Kingdom NR4 7UY

Study participating centre Addenbrooke's Hospital

Hills Road Cambridge United Kingdom CB2 0QQ

Study participating centre Royal Free London Hospital

Pond Street London United Kingdom NW3 2QG

Study participating centre Royal Derby Hospital

Uttoxeter Road Derby United Kingdom DE22 3NE

Study participating centre Yeovil District Hospital

Higher Kingston Yeovil United Kingdom BA21 4AT

Study participating centre Royal Victoria Infirmary

Queen Victoria Road Newcastle Upon Tyne United Kingdom NE1 4LP

Study participating centre Harrogate District Hospital

Lancaster Park Road Harrogate United Kingdom HG2 7SX

Study participating centre Calderdale and Huddersfield Hospital

Acre Street Lindley Huddersfield United Kingdom HD3 3EA

Study participating centre Peterborough City Hospital

Edith Cavell Campus Bretton Gate Peterborough United Kingdom PE3 9GZ

Study participating centre Airedale General Hospital

Skipton Road Steeton Keighley United Kingdom BD20 6TD

Study participating centre Ashford and St Peter's Hospitals

London Road Stanwell Ashford United Kingdom TW15 3AA

Study participating centre

John Radcliffe Hospital

Headley Way Headington Oxford United Kingdom OX3 9DU

Study participating centre Milton Keynes University Hospital

Standing Way Eaglestone Milton Keynes United Kingdom MK6 5LD

Study participating centre Blackpool Teaching Hospitals

Whinney Heys Road Blackpool United Kingdom FY3 8NR

Study participating centre Royal Cornwall Hospital

Treliske Truro United Kingdom TR1 3LJ

Study participating centre Royal Berkshire Hospital

London Road Reading United Kingdom RG1 5AN

Study participating centre Sheffield Teaching Hospitals

Glossop Road Broomhall Sheffield United Kingdom S10 2JF

Study participating centre York Teaching Hospital Wigginton Road

Clifton York United Kingdom YO31 8HE

Study participating centre Doncaster and Bassetlaw Teaching Hospitals

Armthorpe Road Doncaster United Kingdom DN2 5LT

Study participating centre Cwm Taf Morgannwg University Health Board

Ynysmeurig House Navigation Park Abercynon United Kingdom CF45 4SN

Study participating centre Pilgrim Hospital

Sibsey Road Boston United Kingdom PE21 9QS

Study participating centre Lincoln County Hospital

Greetwell Road Lincoln United Kingdom LN2 5QY

Study participating centre Grantham and District Hospital

101 Manthorpe Road Grantham United Kingdom NG31 8DG

Study participating centre Grampian Health Board

Summerfield House 2 Eday Road Aberdeen United Kingdom AB15 6RE

Study participating centre Warrington and Halton Hospital

Lovely Lane Warrington United Kingdom WA5 1QG

Study participating centre Ipswich Hospital

Heath Road
Ipswich
United Kingdom
IP4 5PD

Study participating centre Musgrove Park Hospital

Parkfield Drive Taunton United Kingdom TA1 5DA

Study participating centre NHS Greater Glasgow and Clyde

1055 Great Western Road Glasgow United Kingdom G12 0XH

Study participating centre Royal Blackburn Hospital

Haslingden Road Blackburn United Kingdom BB2 3HH

Study participating centre Sunderland Royal Hospital

Kayll Road Sunderland United Kingdom SR4 7TP

Study participating centre West Suffolk Hospital

Hardwick Lane Bury Saint Edmunds United Kingdom IP33 2QZ

Study participating centre King's College

Denmark Hill London United Kingdom SE5 9RS

Study participating centre St Georges Hospital

Corporation Street Stafford United Kingdom ST16 3SR

Study participating centre

University Hospitals of Morecambe Bay

Burton Road Kendal United Kingdom LA9 7RG

Study participating centre North Cumbria University Hospitals

Newtown Road Carlisle United Kingdom CA2 7HY

Study participating centre Macclesfield District General Hospital

Victoria Road Macclesfield Cheshire United Kingdom SK10 3BL

Sponsor information

Organisation

University Hospitals Coventry and Warwickshire NHS Trust

ROR

https://ror.org/025n38288

Funder(s)

Funder type

Government

Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/167/56

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Rebecca Kearney (R.S.Kearney@warwick.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/01/2024	18/01/2024	Yes	No
Protocol article	protocol	19/11/2020	18/01/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	intervention development	17/06/2021	05/10/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes