ISRCTN63184243 https://doi.org/10.1186/ISRCTN63184243

Acute rehabilitation following traumatic anterior shoulder dislocation

Submission date
03/09/2018

Recruitment status
No longer recruiting

Registration date
07/09/2018

Overall study status
Completed

Last Edited
18/01/2024

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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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Helen Bradley/Anish Patel
artisan@warwick.ac.uk

Study website
https://warwick.ac.uk/fac/sci/med/research/ctu/trials/artisan/health/

Contact information

Type(s)
Scientific

Contact name
Dr Helen Bradley

Contact details
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Clinical Sciences Research Laboratories
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United Kingdom
CV2 2DX
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artisan@warwick.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

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 to request a patient information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/03/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 478; UK Sample Size: 478

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
England

Scotland

United Kingdom

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

Sponsor details
Clifford Bridge Road
Coventry
England
United Kingdom
CV2 2DX
+44 (0)24 765 75386
Sponsorship@warwick.ac.uk

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
It is the trialists' intention to prepare a manuscript for a high impact peer-reviewed journal, which will allow for the results to be disseminated across the orthopaedic and rehabilitation communities, the wider medical community and policy makers.

The trial will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines (www.consort-statement.org).
In addition, the findings of the study will be presented at the following international meetings:
1. European Federation of Orthopaedic and Trauma Associations
2. World Confederation for Physical Therapy

This will be in addition to UK conferences which include:
1. British Elbow and Shoulder Society
2. Orthopaedic Trauma Society
3. British Orthopaedic Association
4. Chartered Society of Physiotherapy

To inform patients and the public, the trialists intend to produce a lay summary, which will be made available in the trial hospitals and to trial participants via an end of trial letter. In addition, they will publicise the work through social media outlets (e.g. Facebook and Twitter) as well as websites such as Patient.co.uk.

The trialists expect the results of this trial to be incorporated into the next iteration of the Cochrane review on 'Conservative management following closed reduction of traumatic anterior dislocation of the shoulder' and national BESS/BOA' Patient Care Pathways: Traumatic anterior shoulder instability'.

HRA guidance on information for participants at the end of a trial will be followed: https://www.hra.nhs.uk/about-us/consultations/closed-consultations/guidance-participant-information-end-study-consultation/

The publication of a trial protocol, methodology papers, trial results and trial data will be in line with the NIHR standard terms and will follow WCTU SOP 22: Publication & Dissemination.

PIS will be available on this webpage: https://warwick.ac.uk/fac/med/research/ctu/trials/artisan/public

Additional documents will be available on this webpage: https://warwick.ac.uk/fac/med/research/ctu/trials/artisan/public
Protocol has not been published yet.

Intention to publish date
30/11/2023

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?
Protocol article	protocol	19/11/2020	18/01/2021	Yes	No
Other publications	intervention development	17/06/2021	05/10/2021	Yes	No
HRA research summary			28/06/2023	No	No
Results article		17/01/2024	18/01/2024	Yes	No