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Pilot trial of steroid injection for shoulder pain

Submission date 17/10/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/10/2012	**Overall study status** Completed	
Last Edited 12/12/2013	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Christy Toms

Contact details
University of Oxford
Department of Primary Health Care
Institute of Health Sciences
Old Road
Headington
Oxford
United Kingdom
OX3 7LF
christy.toms@dphpc.ox.ac.uk

Additional identifiers

EudraCT/CTIS number
2012-000147-27

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13310

Study information

Scientific Title
A single blind randomised controlled pilot trial of corticosteroid injection for shoulder pain

Study objectives
Painful shoulders are a common problem frequently seen in general practice, and a widley used treatment is an injection of a steroid and a local anaesthetic. However, whilst people often seem to benefit from such injections, it is not known for certain whether the steroid itself is actually affective. To be able to answer this definitively a large scale clinical trial is required. However to ensure the success or reliability of such a study and its results we plan to conduct a pilot trial using a small number of participants to identify any feasibility issues that may be encountered. We will recruit participants presenting to their GPs with shoulder pain. Eligible participants will be randomised to receive an injection of the steroid methylprednisolone plus a local anaesthetic (lidocaine) to their shoulder, or just local anaesthetic alone. Both of these medications are currently used for the treatment of shoulder pain. Over a period of three months participants will complete three Oxford Shoulder Score questionnaires, a tool frequently used by clinicians to assess shoulder symptoms. They will also be asked to answer thee 'satisfaction' questions and to report any unexpected effects, good or bad, during the period of their trial participation.

This pilot study will be conducted within the Oxfordshire region and will help us to plan and design a larger trial that will take place over a much wider region with a large number of participants to determine the efficacy of steroid injections in the treatment of shoulder pain.

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=13310

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: 12/SC/0233

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Shoulder pain

Interventions
Baseline Assessment:
Medical History - details of shoulder problem

Eligibility assessment:
Screening and Consent
Completion of follow up questionnaires
Trial injection: either methylprednisolone mixed with lignocaine or lignocaine alone

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Proportion of screened patients eligible to enter the study

Secondary outcome measures
1. Adherence to the allocation treatment
2. Loss to follow up including withdrawal
3. Proportion of eligible patients willing to provide consent
4. Rates of recruitment

Overall study start date
31/08/2012

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Aged 35-74 years old (inclusive)
2. Diagnosed with either rotator cuff tendinopathy or adhesive capsulitis of duration of no more than 6 months
3. Able to complete follow up questionnaires at 2, 4 and 12 weeks

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 50

Key exclusion criteria
1. Pregnancy
2. Breastfeeding
3. The individual has taken part in another research study within the last 12 weeks
4. The individual has already received an injection to the affected shoulder within the last 12 months
5. Established chronic shoulder disorder
6. Previous shoulder surgery on the affected side
7. Evidence of an active infection
8. Currently prescribed anticoagulants
9. Currently prescribed or likely to need systemic corticosteroids for any reason
10. Immuno-compromised
11. Diagnosis of heart failure
12. Uncontrolled diabetes or hypertension
13. Unable to complete follow up questionnaires
14. Allergy to corticosteroids and/or lidocaine
15. Significant disease or disorder which may put the participant at risk

Date of first enrolment
31/08/2012

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Oxford
United Kingdom
OX3 7LF

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details

CTRG
Joint Research Office
Block 60 Churchill Hospital
Headington
England
United Kingdom
OX3 7LJ

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR School for Primary Care Research (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/12/2013		Yes	No
HRA research summary			28/06/2023	No	No