Pilot trial of steroid injection for shoulder pain

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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