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Shoulder acute pain in primary healthcare: injection retraining effective?

Submission date	Recruitment status	[X] Prospectively registered
02/05/2001	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/05/2001	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/11/2010	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G0001147

Study information

Scientific Title

Acronym
SAPPHIRE

Study objectives
Our primary objective is to evaluate whether GP principals should receive extra training in giving injections for shoulder pain. Our secondary objective is to test whether cortisone injections are better than anaesthetic injections.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Primary care

Interventions
We shall invite a random sample of GPs to a training day about injecting shoulders. Half will attend before the trial and the other half after.

We shall randomise eligible patients between:
1. Cortisone injection by a trained GP
2. Cortisone injection by a GP who has received an extra day of training
3. Local anaesthetic injection by a trained GP
4. Local anaesthetic injection by a GP who has received an extra day of training

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Patients will complete two generic instruments (SF-36 & EQ5D) and two specific instruments (British Shoulder Disability Questionnaire (BSDQ) and the Functional Limitations Profile) 1, 3 and 12 months after randomisation.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2002

Completion date
31/03/2006

Eligibility

Key inclusion criteria
1. Patients presenting to GPs with pain in one or both shoulders lasting for less than 3 months who would otherwise have received a steroid injection in primary care
2. Clinical diagnosis of rotator cuff tendonitis based on history of pain in the deltoid area and pain during resisted active movement
3. Patients aged 18 or more
4. Patients who are able and willing and give informed consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
400

Key exclusion criteria
1. Patients whose pain has lasted for more than 3 months
2. Patients who would normally be referred to a rheumatologist in secondary care
3. Patients aged less than 18
4. Patients who are unable or unwilling to give informed consent

Date of first enrolment
01/10/2002

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
School of Medicine
Swansea
United Kingdom
SA2 8PP

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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Sponsor type
Research council

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

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/12/2008		Yes	No
Other publications	cost-effective analysis	01/05/2009		Yes	No