Shoulder Injection Trial - A comparison of injection of Tenoxicam with Depo-Medrone in shoulders with subacromial impingement syndrome

Submission date	Recruitment status No longer recruiting	Prospectively registered	
30/09/2004		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
30/09/2004	Completed	[X] Results	
Last Edited 13/04/2011	Condition category Musculoskeletal Diseases	Individual participant data	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Howard Kwong

Contact details

Orthopaedic Department Hospital of St Cross Barby Road Rugby United Kingdom CV22 5PX +44 (0)1788 572831/545240 htkwong@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0295132803

Study information

Scientific Title

Study objectives

Compare the effects of subacromial injection of Tenoxicam (NSAID) with Depo-medrone (steroid) in patients with impingement syndrome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added as of 27/03/2008:

- 1. Warwick Research Ethics Committee (REC) (ref: RE553)
- 2. Coventry REC (ref: 020/09/03)

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

Musculoskeletal Diseases: Shoulder disorders

Interventions

Please note that, as of 27/03/2008, the end date of this trial was updated from 30/09/2004 to 17/2006 (date on which the last participant was recruited).

Interventions added as of 27/03/2008:

The participants were randomly allocated to the following two arms in equal numbers:

Arm 1: Subacromial injection of tenoxicam (NSAID) 20 mg single dose

Arm 2: Subacromial injection of depo-medrone (steroid) 40 mg single dose

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Primary outcome measures updated as of 27/03/2008:

Constant-Murley shoulder assessment score at baseline and 6 weeks

Primary outcome measures provided at time of registration:

Constant-Murley Shoulder assessment score and Disabilities of the Arm Shoulder and Hand (DASH) Questionnaire.

Secondary outcome measures

Added as of 27/03/2008:

- 1. Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire at baseline and 2, 4 and 6 weeks
- 2. Oxford shoulder score at baseline and 2, 4 and 6 weeks

Overall study start date

15/02/2004

Completion date

17/07/2006

Eligibility

Key inclusion criteria

Added as of 27/03/2008:

- 1. Patients over the age of 18 years
- 2. Clinical diagnosis of subacromial impingement syndrome
- 3. Symptoms lasting longer than 3 months

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Number of participants recruited as of 27/03/2008: 58. At time of registration: 126.

Key exclusion criteria

Added as of 27/03/2008:

- 1. Evidence of other pathology causing shoulder pain
- 2. Injection in the same shoulder within the previous 6 months
- 3. Patients taking regular systemic NSAIDs or steroids or in whom those drugs were contraindicated
- 4. If their present shoulder condition was the subject of any legal proceedings or insurance claims
- 5. Pregnant and breast-feeding mothers

Date of first enrolment

15/02/2004

Date of final enrolment

17/07/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Orthopaedic Department

Rugby United Kingdom CV22 5PX

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

University Hospitals Coventry and Warwickshire NHS Trust

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	01/01/2010		Yes	No