ISRCTN61749398 https://doi.org/10.1186/ISRCTN61749398

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

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

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 /07/2006 (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