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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

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Additional identifiers

Protocol serial number
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)

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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(s)
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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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

United Kingdom

England

Study participating centre
Orthopaedic Department
Rugby
United Kingdom
CV22 5PX

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
University Hospitals Coventry and Warwickshire NHS Trust

Results and Publications

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