

# A randomised, double-blinded, controlled trial of ultrasound guided and conventional clinical examination guided intra-articular corticosteroid injection of large and medium synovial joints in inflammation arthritis

<b>Submission date</b> 27/10/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/04/2011	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

K0586

# Study information

## Scientific Title

### Study objectives

Intra-articular corticosteroid injections in inflammatory arthritis do not always result in clinical improvement in the joint injected, accuracy of injection may be important for a good clinical outcome. Musculoskeletal ultrasound guided injections may be more accurate than clinical examination guided injections. We therefore hypothesise that the group receiving musculoskeletal ultrasound guided intra-articular corticosteroid injections will have a better clinical outcome than the group receiving clinical examination guided injections.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Initial ethical approval was given in November 2004 by Northumberland LREC (ref: 04\Q0902\34).

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

All inflammatory arthritides

### Interventions

Intra-articular corticosteroid injection either guided by musculoskeletal ultrasound or clinical examination.

### Intervention Type

Drug

### Phase

Not Specified

## **Drug/device/biological/vaccine name(s)**

Corticosteroid injection

## **Primary outcome measure**

The primary endpoint of the study is the degree of improvement in loss of function at day 14 measured using a visual analogue scale.

## **Secondary outcome measures**

The secondary endpoints are:

### **1. Clinical:**

- a. The degree of improvement in pain and in stiffness at day 14
- b. The number of responders (patients who improve but do not relapse) at day 14
- c. The degree of improvement in pain, stiffness and loss of function at six weeks
- d. The number of responders at six weeks and at three months
- e. The time to relapse as measured by the time from the joint injection to the first documentation of relapse of joint pain and/or stiffness (as assessed by patient and investigator)
- f. Improvement in movement of joint in all planes (as assessed by goniometer) at day 14 and week six
- g. The safety endpoint is the occurrence of tissue atrophy, nerve or vascular damage or septic arthritis

### **2. Radiological:**

- a. The number of accurately injected joints as assessed by plain radiography
- b. The degree in reduction of ultrasound findings of joint effusion, synovial thickness and power Doppler signal in the injected joint

### **3. Laboratory:**

- a. The reduction in C-reactive protein at 14 days
- b. The reduction in serum MMP-1 and MMP-3 at 14 days
- c. The reduction in serum C-terminal telopeptide of type I collagen (CTX) (a marker of bone resorption) and N-propeptide of type I collagen (PINP) (a marker of bone formation) at 14 days

## **Overall study start date**

05/01/2005

## **Completion date**

01/10/2006

# **Eligibility**

## **Key inclusion criteria**

1. Patients who fulfil the American Rheumatology Association (ARA) Criteria for Rheumatoid Arthritis (RA) or have an established diagnosis of inflammatory arthritis
2. Age greater than 16 years
3. Presentation with an exacerbation of pain and/or stiffness and/or local findings of synovitis (at least two out of the three) of one of either the shoulder, elbow, wrist, knee or ankle joint (hip is excluded as we believe it should only be injected with imaging guidance)
4. Patients must be able to comply with the protocol and give their written informed consent to participate

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

240 (90 patients in each group plus estimated 25% drop out)

**Key exclusion criteria**

1. Radiological evidence of severe joint disease as assessed by previous x-ray of the affected joint
2. Patients receiving treatment for RA and not stabilised on Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), Disease Modifying Anti-Rheumatic Drugs (DMARDs) and/or corticosteroid therapy for one month or longer
3. Evidence of co-existent sepsis
4. A second joint requiring immediate corticosteroid injection
5. An acute flare of RA deemed severe enough by the patients supervising clinician to require an alteration in DMARD therapy
6. Use of intra-articular or intra-muscular steroids in the 28 days prior to study entry
7. Allergy to corticosteroids or contrast material

**Date of first enrolment**

05/01/2005

**Date of final enrolment**

01/10/2006

**Locations****Countries of recruitment**

Ireland

United Kingdom

**Study participating centre**

Consultant Rheumatologist and Physician

Dublin

Ireland

Dublin 24

**Sponsor information**

**Organisation**

Newcastle Hospitals NHS Trust (UK)

**Sponsor details**

Freeman Hospital  
Heaton Road  
Newcastle upon Tyne  
England  
United Kingdom  
NE7 7DN

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.newcastle-hospitals.org.uk/>

**ROR**

<https://ror.org/05p40t847>

**Funder(s)****Funder type**

Charity

**Funder Name**

Arthritis Research Campaign (UK) (reference number 16149)

**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?
<a href="#">Results article</a>	results	01/07/2010		Yes	No