

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

Submission date
27/10/2006

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
26/01/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
28/04/2011

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

Dr David Kane

Contact details

Consultant Rheumatologist and Physician
Adelaide and Meath Hospital (Incorporating the National Children's Hospital)
Tallaght
Dublin
Ireland
Dublin 24

Additional identifiers

Protocol serial number

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).

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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

United Kingdom

Ireland

Study participating centre

Consultant Rheumatologist and Physician

Dublin

Ireland

Dublin 24

Sponsor information

Organisation

Newcastle Hospitals NHS Trust (UK)

ROR

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

Funder(s)

Funder type

Charity

Funder Name

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	01/07/2010		Yes	No