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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

Registration date
26/01/2007

Last Edited
28/04/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 improvment 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 arthritidies

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 gonioimeter) 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?
Results article	results	01/07/2010		Yes	No