

Intensive management versus standard care in early psoriatic arthritis

Submission date 23/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/06/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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
2007-004757-28

IRAS number

ClinicalTrials.gov number
NCT01106079

Secondary identifying numbers
5221

Study information

Scientific Title

A randomised controlled trial to compare intensive management versus standard care in early psoriatic arthritis

Acronym

TICOPA

Study objectives

Tight control versus standard care of early psoriatic arthritis (less than 24 months disease duration).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Northern and Yorkshire Research Ethics Committee (REC), 01/02/2008, ref: 07/H0903/72

Study design

Randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions

A total of 206 patients will be randomised on an equal basis to receive either intensive management (4 weekly review) or standard care (12 weekly review). Each patient will participate in the study for 48 weeks. Those subjects randomised to the tight control arm will be reviewed every 4 weeks (by the PI at each site or a designated researcher) and will be treated according to a rapidly escalating regime, involving standard DMARDs and biologics. Initial therapy will be with oral methotrexate.

Follow up length: 12 months
Study entry: Single Randomisation only

Intervention Type

Other

Phase

Phase IV

Primary outcome measure

The percentage of study patients achieving an ACR 20 response at 12 months

Secondary outcome measures

Changes in clinical response over 6 and 12 months

Overall study start date

01/05/2008

Completion date

01/01/2013

Eligibility

Key inclusion criteria

1. Consultant diagnosis of psoriatic arthritis (PsA)
2. Disease duration less than 24 months
3. Active disease
4. Aged over 18 years, either sex
5. Able to consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 206; UK Sample Size: 206

Key exclusion criteria

1. Previous treatment with disease modifying anti-rheumatic drugs (DMARDs) for PsA
2. Under the age of 18 years
3. Pregnant women or planning pregnancy
4. Recent use of investigational drug

Date of first enrolment

01/05/2008

Date of final enrolment

01/01/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Leeds

Leeds

United Kingdom

LS2 9JT

Sponsor information

Organisation

University of Leeds (UK)

Sponsor details

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Leeds

England

United Kingdom

LS2 9JT

Sponsor type

University/education

Website

<http://www.leeds.ac.uk>

ROR

<https://ror.org/024mrxd33>

Funder(s)

Funder type

Industry

Funder Name

Arthritis Research UK

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Funder Name

Pfizer UK

Alternative Name(s)

Pfizer Ltd, Pfizer Limited

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

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?
Protocol article	protocol	21/03/2013		Yes	No
Results article	results	19/12/2015		Yes	No
Results article	results	01/10/2017		Yes	No