ISRCTN30147736 https://doi.org/10.1186/ISRCTN30147736

Intensive management versus standard care in early psoriatic arthritis

Submission date	Recruitment status
23/04/2010	No longer recruiting
Registration date	**Overall study status**
23/04/2010	Completed
Last Edited	**Condition category**
14/06/2017	Musculoskeletal Diseases

[_] Prospectively registered
[X] 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

Contact name
Ms Nuria Navarro Coy

Contact details
Senior Trial Manager
Clinical Trials Research Unit
University of Leeds
Leeds
United Kingdom
LS2 9JT

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
-
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