

Objective assessment of the remission state and Predictors of sustained Remission in Rheumatoid Arthritis: leading to development of new management guidelines

Submission date 15/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/04/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/01/2012	Condition category 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

Prof Paul Emery

Contact details

c/o Dr Benazir Saleem
Academic Unit of Musculoskeletal Disease
2nd Floor, Chapel Allerton Hospital
Chapeltown Road
Leeds
United Kingdom
LS7 4SA
+44 (0)113 392 4883
benazir_saleem@yahoo.co.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

OPRRA

Study objectives

The presence of sustained clinical remission is dependant on objective imaging and immunological characteristics of remission.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Harrogate Local Research Ethics Committee on th 21st September 2005 (ref: 05/Q1107/57).

Study design

Prospective observational study of two cohorts: early rheumatoid arthritis patients, and established rheumatoid arthritis patients

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

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

Health condition(s) or problem(s) studied

Rheumatoid arthritis

Interventions

1. Withdrawal of anti-TNF therapy
2. Ultrasound of hands of dominant hand

3. Metacarpophalangeal joints two to five and wrist
4. X-ray of hands and feet
5. Blood tests for immunological assessment

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The number of patients experiencing flare of disease at six months (defined as an increase in DAS28 more than 1.2 or to a total DAS more than 2.6).

Secondary outcome measures

1. Change in damage at six months when compared to baseline as measured by X-ray of both hands and feet (modified Sharpe Van de Heijde score) and ultrasound
2. Change in clinical and laboratory markers of disease activity, function and quality of life
3. Assessment of regulatory T cell levels in remission patients
4. Flare of disease by 12 months

Overall study start date

01/12/2005

Completion date

01/06/2008

Eligibility

Key inclusion criteria

1. Aged over 18 years
2. Male or female
3. American College of Rheumatology (ACR) diagnosis of rheumatoid arthritis
4. Stable Tumor Necrotising Factor (TNF) antagonist and concomitant Disease Modifying Anti-Rheumatic Drugs (DMARDs) (e.g. methotrexate treatment for six months)
5. Clinical remission for six months (at time of screening) as defined by Disease Activity Score (DAS28) less than 2.6
6. No clinical indication to change current treatment

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Patients who are unwilling or unable to give consent
2. Patients who are pregnant

Date of first enrolment

01/12/2005

Date of final enrolment

01/06/2008

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

c/o Dr Benazir Saleem

Leeds

United Kingdom

LS7 4SA

Sponsor information**Organisation**

University of Leeds (UK)

Sponsor details

c/o Clare Skinner

Research Grants Manager

School of Medicine

Leeds

England

United Kingdom

LS2 9JT

+44 (0)113 3434897

c.e.skinner@leeds.ac.uk

Sponsor type

University/education

Website

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

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Abbott Laboratories Ltd (UK)

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	01/07/2009		Yes	No
Results article	results	01/09/2010		Yes	No
Results article	results	01/05/2011		Yes	No