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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

Registration date
30/04/2007

Overall study status
Completed

Last Edited
24/01/2012

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

Contact name
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Additional identifiers

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

Study type(s)
Screening

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(s)
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).

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
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Leeds
United Kingdom
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Sponsor information

Organisation
University of Leeds (UK)

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Industry

Funder Name
Abbott Laboratories Ltd (UK)

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