

Remission induction study in early Rheumatoid Arthritis (RA)

Submission date 14/10/2010	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 09/11/2010	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 24/03/2011	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Maurice Barry

Contact details
Dept of Rheumatology
Connolly Hospital
Blanchardstown
Dublin
Ireland
15

Additional identifiers

Protocol serial number
Protocol version 2

Study information

Scientific Title
Randomised controlled trial of etanercept and methotrexate in very early rheumatoid arthritis with sustained remission after etanercept withdrawal

Study objectives

The hypothesis of this study is that remission can be induced at higher rates when patients are treated with combination etanercept and methotrexate from baseline and that remission can be successfully maintained after withdrawal of etanercept.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Connolly Hospital Ethics Board

Primary study design

Interventional

Study design

Randomised open label pilot study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Rheumatoid arthritis

Interventions

Two groups of 20 patients followed for 48 weeks initially.

1. Methotrexate only at dose of 20mg/week.

2. Combination of methotrexate and etanercept 50mg once weekly for 24 weeks; etanercept is withdrawn at 24 weeks if the patient is in remission with DAS28 <2.6.

Patients seen at baseline, 4, 12, 24, 32 and 48 weeks.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Percentage of patients in DAS28 remission (<2.6) at 24 and 48 weeks

Key secondary outcome(s)

1. Percentage of patients achieving ACR20, 50 and 70 scores of improvement

2. Radiographic progression measured by the van der Heijde modified Sharp Score

Completion date

31/12/2010

Eligibility**Key inclusion criteria**

1. Age between 18-80

2. Fulfil 1987 American College of Rheumatology (ACR) classification criteria for RA

- 3. Active disease
 - 3.1. At least 6 swollen and tender joints
 - 3.2. Raised erythrocyte sedimentation rate (ESR)
 - 3.3. C-reactive protein (CRP)
 - 3.4. Prolonged early morning stiffness
- 4. Symptom duration between 6-52 weeks

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

80 Years

Sex

All

Key exclusion criteria

- 1. Other type of inflammatory arthritis
- 2. Connective tissue disease
- 3. Pregnancy/lactation
- 4. Active tuberculosis (TB)
- 5. Pulmonary fibrosis
- 6. Chronic Kidney Disease, eGR<30mls/min
- 7. Chronic liver disease
- 8. History of malignancy treated within the last 5 years, ever diagnosed with melanoma
- 9. Septic arthritis
- 10. Chronic leg ulcers
- 11. Heart failure New York Heart Association (NYHA) class III or IV
- 12. Demyelinating disease

Date of first enrolment

01/07/2006

Date of final enrolment

31/12/2010

Locations**Countries of recruitment**

Ireland

Study participating centre
Dept of Rheumatology
Dublin
Ireland
15

Sponsor information

Organisation
Connolly Hospital (Health Service Executive [HSE]) (Ireland)

ROR
<https://ror.org/03h5v7z82>

Funder(s)

Funder type
Industry

Funder Name
Wyeth pharmaceuticals Ltd. (Ireland) - Unrestricted research grant for Dr. C Sheehy

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration