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Remission induction study in early Rheumatoid Arthritis (RA)

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

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised open label pilot study

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 contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
Two groups of 20 patients followed for 48 weeks initally.
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 Combination of methotrexate and etanercept 50mg once weekly for 24 weeks; etanercept is withdrawn at 24 weeks if the patient is in remission with DAS28 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 measure
Percentage of patients in DAS28 remission (<2.6) at 24 and 48 weeks

Secondary outcome measures
1. Percentage of patients achieving ACR20, 50 and 70 scores of improvement
2. Radiographic progression measured by the van der Heijde modified Sharp Score

Overall study start date
01/07/2006

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
40

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
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Sponsor information

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

Sponsor details
Connolly Hospital,
Blanchardstown
Dublin
Ireland
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Sponsor type
Hospital/treatment centre

Website
http://www.connollyhospital.ie

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

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