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Leflunomide or methotrexate plus subcutaneous tumour necrosis factor-alpha (TNF-alpha) blocking agents in rheumatoid arthritis

Submission date 18/05/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 06/07/2010	**Overall study status** Completed	
Last Edited 06/07/2010	**Condition category** Musculoskeletal Diseases	

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

N/A

Study information

Scientific Title
Comparison between leflunomide or methotrexate plus subcutaneous tumour necrosis factor-alpha (TNF-alpha) blocking agents in rheumatoid arthritis: a two year open label study

Study objectives
To compare the effectiveness and safety of a therapeutic regimen associating subcutaneous anti-tumour necrosis factor-alpha (anti-TNF-alpha) agents etanercept (ETN) and adalimumab (ADA) with leflunomide (LEF) or methotrexate (MTX), in a two year open-label study performed in clinical practice.

Background information:
New biological disease-modifying antirheumatic drugs (DMARDs) became available in 1999, including agents targeting anti-TNF-alpha agents. Among these, infliximab (INF), etanercept (ETN) and adalimumab (ADA) have been shown to reduce signs and symptoms of RA and to protect joints from structural damage in double-blind placebo-controlled randomised trials. Certain anti-TNF-alpha agents can be prescribed alone, but randomised trials have consistently demonstrated that the efficacy of these biological agents is significantly increased by concomitant MTX. However, not all patients tolerate or respond to MTX, and anti-TNF-alpha agents are commonly prescribed with DMARDs other than MTX in clinical routine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethical committee of ASL10 Florence approved in 2005 (ref: CTS/2005/31057)

Study design
Randomised open label active controlled 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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Rheumatoid arthritis (RA)

Interventions
Leflunomide 20 mg/ day or methotrexate 10-15 mg/ once week plus etanercept 50 mg /once week or adalimumab 14 mg/ every other week.
Total duration 104 weeks.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Etanercept, adalimumab, leflunomide, methotrexate

Primary outcome measure
All patients were assessed at the beginning of the study (baseline) and every 3 months for 2 years by measuring 28-item Disease Activity Scale (DAS-28) score and DAS-CRP score. Remission was considered for a value less than 2.6 while low disease activity was considered for a value between 2.6 and 3.2.

Secondary outcome measures
Effectiveness and safety of both groups assessed using the value of DAS 28 and DAS-CRP score every 6 months.

Overall study start date
05/05/2005

Completion date
20/09/2007

Eligibility

Key inclusion criteria
1. Adult patients (aged between 26 and 86 years, either sex) with active rheumatoid arthritis (RA) defined as follows: greater than or equal to 6 swollen joints and greater than or equal to 6 painful joints and at least two of the following:
1.1. Morning stiffness greater than or equal to 45 minutes
1.2. Erythrocyte sedimentation rate (ESR) greater than or equal to 28 mm/first hour
1.3. C-reactive protein (CRP) greater than or equal to 2.0 mg/dL
2. Stabilised low-dose of prednisone (less than or equal to 7.5 mg)
3. Stable dose of non-steroidal anti-inflammatory drugs (NSAIDs)
4. Intrarticular injections of corticosteroids not allowed

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
96 undifferentiated Caucasian patients

Key exclusion criteria
Patients in stable therapy with LEF or MTX with a non-controlled disease activity with association therapy using a biological infusion (infliximab, rituximab, abatacept) or with a high dose of prednisone (greater than 10 mg)

Date of first enrolment
05/05/2005

Date of final enrolment
20/09/2007

Locations

Countries of recruitment
Italy

Study participating centre
Ospedale S. Giovanni di Dio
Florence
Italy
50122

Sponsor information

Organisation
St John of God Hospital (Ospedale S. Giovanni di Dio) (Italy)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01c1ce922

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St John of God Hospital (Ospedale S. Giovanni di Dio) (Italy)

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