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Clinical and ultrasonographic efficacy of low-dose prednisone co-treatment versus methotrexate alone in early rheumatoid arthritis

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Registration date 25/10/2010	**Overall study status** Completed	
Last Edited 25/10/2010	**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
Clinical and ultrasonographic efficacy of low-dose prednisone co-treatment versus methotrexate alone in early rheumatoid arthritis: an open label randomised clinical trial with parallel design

Acronym
RAREmission

Study objectives
The use of corticosteroids (CS) in association with conventional disease modifying anti-rheumatic drugs (DMARDs) is strongly recommended in the treatment of rheumatoid arthritis (RA) and other rheumatic diseases after a careful evaluation of patients risk to benefit ratio.

In particular in RA, CS show a rapid symptomatic effect on inflammatory symptoms (pain and general well-being) and help in controlling objective signs of inflammation (tender and swollen joints).

Several studies also support disease modifying properties for CS, in terms of prevention of future joint damage in early RA, both for initial short-time high dosages followed by step down schedules and for low-dose oral therapy.

On the whole, in clinical trials involving early-onset RA patients treated with low-dose oral CS in association with DMARDs, clinical and functional benefits last only few months after the start of treatment, fading away thereafter, whilst prevention of structural damage persists over a longer time.

Thus, these studies on CS therapy in RA seem to point at the very same conclusion, suggesting a sort of dissociation between the short-term unsustained clinical response against the long lasting effect on radiographic progression.

This might be due both to a partial dissociation between clinically detectable joint inflammation and structural damage, and to a deeper effect of CS in reducing synovial inflammation and subsequent joint destruction.

Ultrasensitive imaging techniques may help in testing this hypotheses. Recent imaging studies on RA have demonstrated that the structural progression observed in patients in clinical remission might be explained by the persistency of a subclinical signs of synovitis detected by magnetic resonance imaging or ultrasonography (US). In particular, Power-Doppler ultrasonography (PDUS), which measures the amount of intrarticular blood flow, has been demonstrated to be a valid and reliable tool in detecting subclinical inflammation in RA, and it is believed to be an objective measure of activity of joint inflammation.

However, only a few uncontrolled studies have tested the effect of CS on US-detected joint inflammation, showing rapid improvement of US-detected synovial inflammation after intra-articular and intravenous CS treatment in established RA.

At present there is no evidence about the effect of low dose oral CS on the US-detected synovial inflammation.

This study aimed to verify, in patients with recent-onset RA, the effect of low doses of oral prednisone on clinical and US outcomes over 12 months of follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethical Committee of the IRCCS Policlinico San Matteo Foundation of Pavia approved on the 8/05/2007 (ref: P-20070011051)

Study design
Open label randomised clinical trial with parallel design

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

Interventions
Steroid arm: prednisone (Deltacortene) 12.5 mg/day for 2 weeks and then 6.25 mg + Methotrexate 10mg/week
No steroid arm: Methotrexate 10mg/week.

Drug escalation after 2-4-6-9 months for every group: MTX escalation to 15mg/week and to 20mg/week if lack of achievement of low-disease activity (DAS<2.4).

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Prednisone, methotrexate

Primary outcome measure

1. Clinical remission (DAS<1.6), measured at 12 months
2. Ultrosonographic remission (PD=0), measured at 12 months

Secondary outcome measures
measured at 12 months:
1. Mean decrease in swollen joint count
2. Tender joint count
3. ESR
4. CRP
5. Power Doppler scores

Overall study start date
01/01/2006

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Fulfilment of the American College of Rheumatology (ACR) classification criteria for RA
2. Aged greater than 18 years, either sex
3. Symptom duration less than 12 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
220

Key exclusion criteria
Contraindications for glucocorticoid therapy, including uncontrolled diabetes and previous fragility osteoporotic fractures

Date of first enrolment
01/01/2006

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Italy

Study participating centre
Piazzale Golgi 19
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Sponsor information

Organisation
IRCCS Policlinico San Matteo (Italy)

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Sponsor type
Not defined

Website
http://www.www.unipv.it

ROR
https://ror.org/05w1q1c88

Funder(s)

Funder type
University/education

Funder Name
University of Pavia (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