Treatment Intensification Based on Disease Activity Parameters or on Cartilage Breakdown Markers in Early Rheumatoid Arthritis.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28499

Source
NTR

Brief title
N/A

Intervention

Outcome measures

Primary outcome

1. DAS: Disease activity score (28 joints) calculated from swollen and tender joint counts, ESR, patient global assessment of disease activity (10 cm VAS);

2. CTX-2: measured in spot urine (delivered 1 week before visit) together with creatinine (method Garnero, Lyon).

Secondary outcome

1. WHO/ILAR core set; DAS remission, EULAR improvement; ACR remission, ACR20,etc; EuroQoL;

2. Efficacy Self assessment: RADAI joint score, fatigue VAS;

3. Bone Mass: DEXA lumbar spine; Right hip (neck).

Study description

Background summary

N/A

Study objective

In early RA, does treatment intensification (by conventional and biological means) aimed at keeping urine CTX-2 levels below 150 nmol/µmol creatinine lead to a lower radiological progression than treatment intensification aimed at keeping DAS28 at or below 3.2?

Study design

N/A

Intervention

The study design randomizes to two monitoring strategies that lead to subsequent steps in the treatment schedule: either clinical monitoring by Disease Activity Score (DAS28) to achieve and keep the DAS below 2.6 (clinical remission); or: Lab monitoring by CTX-2 to achieve and keep the urinary level of CTX-2 below 150 ng/µmol creatinine.
All patients will receive 'traditional' combination DMARD therapy (Disease-Monifying Antirheumatic Therapy) for a minimum of 22 weeks: step 1 is evaluated at week 8, and step 2 at week 22.

Patients will receive treatment intensification according to achieved levels of DAS28 (DAS group) or according to achieved levels of CTX-2 (CTX group).

Contacts

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Eligibility criteria

Inclusion criteria

Patients must have:

1. Rheumatoid arthritis (ACR criteria met cumulatively);

2. Requiring treatment: DAS28 >3.2;

3. Propensity for radiographic progression: urinary CTX-2 > 150 ng/µmol creatinine.

Exclusion criteria

1. Unwillingness to participate in the study and comply with its procedures by signing a written informed consent;

More chance of harm

2. Contraindication to study drugs

a. Previous serious adverse reaction or documented allergy to any of the trial drugs or their constituents;

b. Previous inability to tolerate sulphasalazine (minimum 1g/d), hydroxychloroquine (minimum 200mg/d) methotrexate (minimum 7.5mg/week) or oral prednisolone;

3. Active infection or those at high risk of infection;

a. Abnormal chest X-ray or positive tuberculin test suggestive of previous TB that has not been adequately treated;

b. Chronic leg ulcers;

c. Septic arthritis of a native joint within the last 12 months;

d. Previous prosthetic joint sepsis within the last 12 months, indefinitely if prosthesis remains in situ;

e. Bronchiectasis, indwelling urinary catheter and other situation deemed high risk by treating physician;

4. Malignancy, excluding basal cell carcinoma and malignancies diagnosed and treated more than 10 years previously, in whom there is a high probability of cure in the opinion of the treating physician;

5. Pregnancy, planned pregnancy or lactation. Women of childbearing age (includes women who are less than 1 year postmenopausal and women who become sexually active) must be using an acceptable method of birth control (e.g., hormonal contraceptive, medically prescribed IUD, condom in combination with spermicide) or be surgically sterilized (e.g., hysterectomy or tubal ligation);

6. Current signs or symptoms of severe, progressive, or uncontrolled renal, haematological, hepatic, respiratory, gastrointestinal, endocrine, cardiac, neurological or cerebral disease. Specifically, this includes cardiac failure (NYHA class 3 or 4);

7. Screening blood tests at baseline which show haemoglobin < 8g/l, total WBC < 3.5 or neutrophils < 1.5, platelets < 100. Patients will also be excluded if serum ALT or alkaline phosphatase are more than twice the upper limit of normal, or impaired renal function: creatinine > 100 mumol/L AND Cockroft creatinine clearance < 40 ml/min;

8. Subjects who have used any investigational product within 30 days prior to enrollment;

9. Age < 18;

Less chance of benefit

10. Disease duration > 36 months (date of diagnosis by rheumatologist);

11. Previous treatment of RA with more than two DMARDs. Systemic glucocorticoids are counted as DMARDs. Treatment is defined as a cumulative period of 8 weeks or more;

Measurement difficulties

12. Insufficient command of local language;

13. Illiteracy;

14. Inability to comply with the protocol (opinion of treating physician).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2003
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	13-05-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL51
NTR-old	NTR80
Other	: P03627
ISRCTN	ISRCTN96372677

Study results

Summary results
N/A