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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28499

Bron
NTR

Verkorte titel
N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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?

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2003
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	13-05-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A