IMPROVED: Induction therapy with Methotrexate and Prednisone in Rheumatoid Or Very Early arthritic Disease.

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There is a clinically and statistically significant difference in the percentage of patients who achieve and maintain clinical remission (defined as DAS < 1.6) and in functional ability and progression of radiological joint damage after 1 year of...

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20953

Bron
Nationaal Trial Register

Verkorte titel
IMPROVED

Aandoening

Recent onset rheumatoid arthritis (RA) and undifferentiated arthritis (UA)

Ondersteuning

Primaire sponsor: Abbott

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percentage of patients in remission (DAS <1.6), functional ability as measured by HAQ, radiological damage progression as measured by Sharp/van der Heijde score.

Toelichting onderzoek

Achtergrond van het onderzoek

In patients with recently diagnosed rheumatoid arthritis or undifferentiated arthritis treatment will commence with a combination of methotrexate and a high tapered dose of prednisone. If after 4 months clinical remission (DAS <1.6) is not achieved, patients will receive treatment with either A) an extended combination therapy (methotrexate, sulphasalazine, hydroxychloroquine and a repeated high tapered dose of prednisone) or with B) a combination of methotrexate and adalimumab, a TNF-blocking agent. If a DAS <1.6 is not achieved, patients treated according to A) will cross over to treatment B), patients in B) will receive a dose increase of adalimumab. If at any 4-monthly evaluation a DAS <1.6 is achieved, patients will start to taper and finally stop all medication. Study outcomes after 1 year of treatment are: percentage of patients with DAS <1.6 (with and without treatment), functional ability (as measured by HAQ) and radiological damage progression (as measured by total Sharp/van der Heijde score).

Doel van het onderzoek

There is a clinically and statistically significant difference in the percentage of patients who achieve and maintain clinical remission (defined as DAS < 1.6) and in functional ability and progression of radiological joint damage after 1 year of follow-up in recent-onset arthritis patients (RA and UA) who, having failed to achieve remission on a combination of methotrexate and a tapered high dose of prednisone, receive extended medication in a combination of methotrexate, sulphasalazine, hydroxychloroquine and low dose prednisone, or who switch to a combination of methotrexate and adalimumab.

Onderzoeksproduct en/of interventie

Four-monthly evaluations of disease activity score and safety. Medication adjustments by protocol, based on DAS calculation, aimed at DAS <1.6 (remission). Initial treatment with methotrexate and a tapered high dose of prednisone. If DAS >1.6, randomisation to either combination with MTX, SSA, hydroxychloroquine and a tapered high dose of prednisone, or combination with MTX with adalimumab. In case of DAS <1.6: taper medication and discontinue if DAS remains <1.6.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients >=18 years of age with either RA according to the revised criteria of the American College of Rheumatology (ACR) (29) of less than two years duration, or UA, suspected by the rheumatologist to have an early presentation of RA;

2. All patients must have at least one (out of 66) swollen joint and at least one other (out of 68) painful joint, and a combined DAS of >1.6;

3. All patients must be DMARD- and corticosteroid naïve.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous therapy with DMARDs or with corticosteroids (exception: one dose of parenteral corticosteroids within the last 6 months, but not within the last 2 months, or an oral dose of prednisone of =<10 mg/day for =< 2 weeks within the same period allowed);

2. Pregnancy or wish to become pregnant during the study, or childbearing potential without adequate contraception;

3. Concomitant treatment with another experimental drug;

4. History or presence of malignancy within the last five years;

5. Bone marrow hypoplasia;

6. Elevated hepatic enzyme levels (ASAT, ALAT > 3 times normal value);

7. Serum creatinine level > 150 umol/l or estimated creatinin clearance of < 75%;

8. Uncontrolled diabetes mellitus (according to the rheumatologist);

9. Uncontrolled hypertension (according to the rheumatologist);

10. Heart failure (NYHA functional class III or IV);

11. Alcohol or drug abuse;

12. History of infected joint prothesis within the previous 3 months;

13. Serious infections, such as hepatitis, pneumonia, pyelonephritis in the previous 3 months;

14. Chronic infectious disease such as chronic renal infection, chronic chest infection with bronchiectasis or sinusitis;

15. History of active tuberculosis requiring treatment within previous 3 years, or signs and symptoms of latent infection with tuberculosis, based on medical history, physical examination, PPD skin test, X-thorax;

16. History of opportunistic infections such as herpes zoster within previous 2 months;

17. Evidence of active cytomegalovirus, active pneumocystis carinii, or drug resistant atypical mycobacterium infection etc;

18. Evidence of hepatitis B infection;

19. Documented HIV infection, AIDS related complex (ARC) or AIDS;

20. History of lymphoproliferative disease including lymphoma or signs suggestive of possible lymphoproliferative disease;

21. Multiple sclerosis or neurological symptoms suspect for demyelinizing disease.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2007
Aantal proefpersonen:	610
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL789
NTR-old	NTR801
Ander register	: 1
ISRCTN	ISRCTN11916566

Resultaten

Samenvatting resultaten
N/A