COBRA-light study, an open randomised trial comparing a modified COBRA therapy with the COBRA therapy according to BeSt in early rheumatoid arthritis.

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Early, aggressive treatment of rheumatoid arthritis with DMARDs has been proven to lower disease activity and suppress radiologic progression. Moreover, combination therapy is shown to be superior to monotherapy. The COBRA therapy is effective in...

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

Samenvatting

ID

NL-OMON26545

Bron
NTR

Verkorte titel
COBRA-light

Aandoening

Rheumatoid arthritis

Ondersteuning

Primaire sponsor: VU medical centre (VUmc) Amsterdam, Department of Rheumatology
Overige ondersteuning: TIPharma, Wyeth

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Difference in delta DAS compared at baseline between the both treatment strategies after 6 months.

Toelichting onderzoek

Achtergrond van het onderzoek

An open, randomised trial comparing two treatment strategies, COBRA and a modified COBRA-schedule, in patients with early RA. The secondary aim of this trial is to study the side effects of glucocorticosteroids on bone-and cartilage metabolism, insulin resistance and metabolic syndrome. A total of 160 patients will be included and treated according to the randomised treatment strategy untill week 52 and followed-up untill week 104.

Doel van het onderzoek

Early, aggressive treatment of rheumatoid arthritis with DMARDs has been proven to lower disease activity and suppress radiologic progression. Moreover, combination therapy is shown to be superior to monotherapy. The COBRA therapy is effective in several trials, and the positive effect on radiologic progression sustained over time. In a recent trial (BeSt) comparing different treatment strategies the COBRA therapy and initial therapy with Infliximab (a TNF-blocker) were equally effective in improving functional ability and preventing radiographic damage. Apparently most rheumatologists and or patients have resistance in prescribing this therapy.

Onderzoeksopzet

At baseline patients will be included and extensively examined. At decision moments, eg weeks 13, 26, 39, 52, 78 and 104, an independent research nurse will perform an assessment of the disease activity. This will be followed by a visit with the treating physician.

Onderzoeksproduct en/of interventie

The study design randomizes the two treatment strategies, ie COBRA or a modified COBRA schedule.
In the first year patients will be seen frequently in order to follow disease-activity, side effects and
cardiovascular parameters. In the first year patients will be seen at 2, 4, 8, 13, 26, 39 en 52 weeks. Treatment will be adjusted according to the DAS44 score. In the

follow-up period of the second year patients will be seen every six months.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Active RA according to ACR criteria,

2. >6 swollen joints or >6 painful joints,

3. Disease duration < 2jr,

4. ESR > 28mm,

5. VAS > 20,

6. Age > 18 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Prior treatment DMARDs (except hydroxychloroquine).

2. Insulin-dependent Diabetes mellitus.

3. Uncontrollable non-insuline dependent diabetes mellitus.

4. Heart failure NYHA class 3-4.

5. Uncontrollable hypertension.

6. ALAT/ASAT > 3 times normal values.

7.Reduced renal function (serum creat > 15mcmol).

8. Contra-indications for methotrexate, sulphasalazine or prednisolone.

9. Indications of probable tuberculosis

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2008
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-02-2008
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	NL1168
NTR-old	NTR1213
Ander register	METC : 2007/150
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A