Tracleer in Behçet's disease

Gepubliceerd: 08-07-2008 Laatst bijgewerkt: 18-08-2022

Therapeutic effect of bosentan in patients with Behçet's disease due to antiinflammatory effects on the vascular wall.

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

Samenvatting

ID

NL-OMON26435

Bron
NTR

Verkorte titel
N/A

Aandoening

Behçet's disease
bosentan
vasculitis
endothelin 1

Ondersteuning

Primaire sponsor: ErasmusMC
Overige ondersteuning: Actelion

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- A decrease in the score in the BDCAF of > 10 in patients with BD with a BDCAF score of > 20

Toelichting onderzoek

Achtergrond van het onderzoek

Patients with Behcet's disease refractory for immunosuppressive therapy (BDCAF >20) are randomized for add on treatment with bosentan for 6 months. Therapeutic efficacy will be measured with a standarized activity scoring system (BDCAF), and analyzed with secundary parameters such as ET-1 levels, cytokines and Tcell functionality.

Doel van het onderzoek

Therapeutic effect of bosentan in patients with Behçet's disease due to antiinflammatory effects on the vascular wall.

Onderzoeksopzet

Week 0, 4, 8, 12, 16, 20, 24, 28, 32

Onderzoeksproduct en/of interventie

Double-blind, randomized.

Bosentan 2 x 125 vs placebo 6 months, follow up 2 more months

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. BD patients classified according to the criteria according to the International study group for BD

2. BD patients not responding to their usual therapy (BDCAF > 20)

3. Non life-or sight threatening active disease.

4. Adequate birth control measures in women of childbearing age during and for 6 weeks after receiving the last administration.

5. The screening laboratory test results must meet the following criteria:

- Hemoglobin ¡Ý 6.5 mmol/L.

- WBC ¡Ý 3.0 x 109/L.

- Neutrophils ¡Ý 1.5 x 109/L.

- Platelets ¡Ý 100 x 109/L.

- SGOT (AST), SGPT (ALT) and alkaline phosphatase levels must be within 3 times the upper limit of normal (ULN) range for the laboratory conducting the test.

- Creatinine clearance > 20 ml/min.

6. Patient must be able to adhere to the study visit schedule and other protocol requirements.

7. The patient must be capable of giving informed consent and the consent must be obtained prior to any screening procedures.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age < 18 years.

2. Women who are pregnant, nursing, or planning pregnancy within 38 weeks after enrollment.

3. Hypotension, defined as systolic blood pressure less than 85 mm Hg

4. Use of any of the following drugs: glybenclamide, calcineurin inhibitors (eg, cyclosporine A, tacrolimus) or fluconazole. Attention must be focused on liverenzymes and adverse effects if the patient uses other drugs that interfere with CYP-450 isoenzymes such as listed in paragraph 11.

5. Use of any investigational drug within 1 month prior to screening or within 5 half-lives of the investigational agent, whichever is longer.

6. Liver enzymes > 3 times the ULN, Creatinine clearance of < 20ml/min.

7. Patients with known hypersensitivity to Bosentan or to drugs with similar chemical structures.

8. Current signs or symptoms of severe, progressive or uncontrolled renal, hepatic, hematological, gastrointestinal, endocrine, pulmonary, cardiac, neurological, infectious or cerebral disease.

9. Malignancy within the past 5 years (except for treated squamous or basal cell carcinoma of the skin without evidence of recurrence).

10. Known recent substance abuse (drugs or alcohol).

11. Poor tolerability of venipuncture or lack of adequate venous access for required blood sampling during the study period.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2008
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-07-2008
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	NL670
NTR-old	NTR1372
Ander register	METC Erasmus MC Rotterdam : 2008-042
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A