Tracleer in Behçet's disease

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26435

Source
NTR

Brief title
N/A

Health condition

Behçet's disease
bosentan
vasculitis
endothelin 1

Sponsors and support

Primary sponsor: ErasmusMC
Source(s) of monetary or material Support: Actelion

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- ET-1 levels in relation with BDCAF.

- Study of cytokine patterns in relation with therapy and BDCAF.

- T cell patterns in relation with therapy and BDCAF.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

Double-blind, randomized.

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-07-2008
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	NL670
NTR-old	NTR1372
Other	METC Erasmus MC Rotterdam : 2008-042
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A