Sandostatin therapy in sarcoidosis

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Sarcoidosis (SA) is a rare systemic disease that is characterized by the formation of granulomas. It can affect any organ in the body. Somatostatin is a peptide hormone that regulates neuroendocrine processes but it also is an intersystem...

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

Samenvatting

ID

NL-OMON25865

Bron
NTR

Verkorte titel
SST in SA

Aandoening

Sarcoidosis, sandostatin
Sarcoïdose, sandostatine

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Department of Internal Medicine.
Overige ondersteuning: Novartis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main endpoint is the change in uptake on somatostatin receptor scan.

Toelichting onderzoek

Achtergrond van het onderzoek

Design:nonrandomized, open label, proof of principal investigator initiated trial.

Subjects:patients with chronic, symptomatic and stable sarcoidosis that show inflammatory activity on somatostatin receptor scan and previously received treatment with corticosteroids.

Study medication:Monthly injections with sandostatin for six months.

Objective: To evaluate efficacy of sandostatin in a subset of patients that are refractory/intolerant to corticosteroid therapy.

Primary endpoint:change in uptake on somatostatin receptor scan.

Secondary enpoints: bloodtests, quality of life score, pulmonary function and skin evaluation.

Doel van het onderzoek

Sarcoidosis (SA) is a rare systemic disease that is characterized by the formation of granulomas. It can affect any organ in the body. Somatostatin is a peptide hormone that regulates neuroendocrine processes but it also is an intersystem signalling molecule on the immune system and is implicated in the pathogenesis of SA. Sandostatin (SST), octreotide is the stable and synthetic analogue of the natural somatostatin. Octreotide has an inhibitory effect of the immune system. Affected locations in SA show octreotide uptake on SRS. As corticosteroids, with all the additional disadvantages, are first-line treatment in sarcoidosis, SST is studied as an alternative treatment for SA.

Onderzoeksopzet

Duration of intervention is six months. Primary endpoint (somatostatin receptor scan) after nine months after initiation therapy. Total folluw up is 12 months.

Onderzoeksproduct en/of interventie

Patients will receive 20 mg of sandostatin injection intramuscular IM every month for six months.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age above 18 years with obtained written consent

2. Have biopsy-proven symptomatic, stable, chronic sarcoidosis for minimal three years.

3. Have a positive SRS

4. Involvement of skin, joint, lymph nodes or lung. Patients with pulmonary involvement have a diffusing capacity between 60 and 75 percent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Corticosteroid use up to three months prior of trial

2. Chronic renal failure defined as a GFR below 50%

3. Liver disease

4. Have an indication for intensifying immunosuppressive therapy; threatening organ damage

5. Have failed on earlier anti TNF-alfa therapy

6. Have an underlying cardiac disease

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2014
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-06-2014
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	NL4520
NTR-old	NTR4655
Ander register	Novartis : MACS2757

Resultaten

Samenvatting resultaten
N/A