Sandostatin therapy in sarcoidosis

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Primary Objective: To evaluate efficacy of SST looking at the change in uptake on SRS in a subset of chronically active patients in which intensification of corticosteroid therapy is not indicated. . Secondary Objective(s): To study the composite...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON40194

Source
ToetsingOnline

Brief title
SST in SA

Condition

- Autoimmune disorders

Synonym
Sarcoidosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Novartis

Intervention

Keyword: efficacy, sandostatin, sarcoidosis, SRS-scan

Outcome measures

Primary outcome

To evaluate efficacy of SST in a subset of patients that are

refractory/intolerant for corticosteroid therapy by a change in uptake on SRS.

Change in uptake in SRS, defined as improved, no change, worse.

Secondary outcome

To study the composite clinical score using the following parameters.

Measurements of ESR, CRP, full blood count, lysozyme, ACE, 25-hydroxyvitamin

D, 1,25-dihydroxyvitamin D3 sIL-2R. Quality of life score assessment with

RAND-36 will be conducted. When applicable lung-function test with FVC and DLCO

and skin evaluation will take place.

Study description

Background summary

The association between somatostatin receptor activity and octreotide uptake on SRS in SA has been described in various reports. SA remains a rare, systemic disease with granulomatous inflammation in various parts of the body. In many cases there is no need for treatment and naturally recovery is seen. However, a subgroup of patients suffer from a chronically active and complicated form of SA that require therapy. These chronic patients that are regularly seen in the Erasmus MC as it is a tertiary referral and *sarcoidosis centre*. First line therapy contains corticosteroids. However, these agents can have serious side effects, on short term it can cause diabetes, but also long-term complications such as osteoporosis are frequently seen. Also, patients can be refractory to this treatment and need more aggressive therapy. The introduction of anti-TNF * agents looked promising a few years ago. Patients can also be non-responders and form auto-antibodies or have allergic reactions to it. Because of the high costs involving this treatment, implementation is limited and still is reserved for a subgroup of patients with SA. Therefore, there is still a need for more therapeutic options. Treatment with SST is worth studying for several reasons. 1.In some patients with active sarcoidosis no effect of conventional therapy is seen or the severity of treatment does not outweigh the side effects. 2.

Sarcoidosis expresses somatostatin receptors that are represented in SRS and treatment with octreotide is proven successful in other somatostatin positive disorders. 3. Somatostatin analogues are proven safe and have relatively few side effects.

Study objective

Primary Objective: To evaluate efficacy of SST looking at the change in uptake on SRS in a subset of chronically active patients in which intensification of corticosteroid therapy is not indicated. .

Secondary Objective(s): To study the composite clinical score using the following parameters: blood test (ESR, CRP, full blood count, lysozyme, ACE, 25-hydroxyvitamin D, 1,25-dihydroxyvitamin D, sIL-2R), quality of life (RAND-36) and when applicable lung function test (FVC, DLCO) and skin evaluation.

Study design

The current study is a nonrandomized, open label trial. The intention is to treat 20 patients with biopsy-proven symptomatic, chronic (>3 years) and stable SA. All patients have a need for maintenance therapy, but not for intensifying therapy towards preventing organ damage.

All 20 patients receive an injection of 20 mg of sandostatin for six months, every month. Before start of study and at two weeks and three and six, nine and twelve months, patients will visit the outpatient clinic for evaluation, measurements of endpoints and collection of adverse events. In case of unsatisfactory response to treatment, SST will be uptitrated to 30 mg injections at month 3.

Inclusion of patients will be started from April 2014 until April 2015. Liverenzymes, TSH and glucose level and ECG will be evaluated before start of treatment and at week two and three and six, nine and twelve months into the program when blood is drawn to measure endpoints. After six injections, treatment is stopped. It is thought that during treatment with SST, SRS will not be reliable as an assessment tool as the receptors are blocked For this reason SRS will be conducted at month nine when patients are free of SST treatment for three months. SST will be restarted in case of a good clinical response and relapse after cessation of treatment.
In order to evaluate the efficacy of SST, patients will be actively followed during therapy and in the six months following treatment. Then, statistical analysis and writing of the scientific article will take place.

Intervention

Treatment with Sandostatin LAR 20 mg injections every months for six months.

Study burden and risks

Patients with SA may suffer from various symptoms, some more severe than others. Treatment remains difficult in a group of SA patients, specifically in chronic disease. SST may potentially be a target for therapy as patients express somatostatin on SRS. Therefore, the efficacy of SST is studied in chronic, symptomatic SA patients. Patients may directly benefit from this trial. Adverse events are well documented and will be closely monitored. SST is considered a safe agent and is studied and used for many years. Patients with SA visit the outpatient clinic on a regular basis, every three months. For this trial, patients will visit the clinic one extra time, at two weeks into the study. The extra volume of bloodwithdrawal and extra pulmonary function test is considered a very light burden. SRS is a moderate burden considering the use of laxatives and duration of the scan, however it has an acceptable radiation load.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age above 18 years with obtained written consent
* Have biopsy-proven symptomatic, stable, chronic sarcoidosis for minimal three years.
* Have a positive SRS
* Involvement of skin, joint, lymph nodes or lung. Patients with pulmonary involvement have a diffusing capacity between 60 and 75 percent.

Exclusion criteria

* Corticosteroid use up to three months prior of trial
* Chronic renal failure defined as a GFR below 50%
* Liver disease
* Have an indication for intensifying immunosuppressive therapy; threatening organ damage
* Have failed on earlier anti TNF-* therapy
* Have an underlying cardiac disease

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-07-2014

Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Sandostatin LAR
Generic name:	nvt
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	27-02-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-06-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-02-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2013-005376-17-NL
CCMO	NL47391.078.14