SOM230 Graves Orbitopathy pilot trial

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Therefore, we aim to investigate in a pilot trial the effect of SOM230 on predefined endpoints in patients with moderate to severe GO whom have contraindications for prednisolone therapy or decline from prednisolone therapy for other reasons.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Thyroid gland disorders
Study type	Interventional

Summary

ID

NL-OMON38562

Source
ToetsingOnline

Brief title
SOMGO

Condition

- Thyroid gland disorders
- Autoimmune disorders

Synonym
Graves Orbitopathy/Eye Disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Novartis

Intervention

Keyword: graves ophthamopathy, graves orbitopathy

Outcome measures

Primary outcome

Predefined combined clinical endpoints: see protocol.

Secondary outcome

n.a.

Study description

Background summary

Graves* ophthalmopathy (GO), or Graves Orbitopathy, is clinically present in ~25% of patients with Graves* disease (hyperthyroidism). There is consensus that patients with active, moderate-to-severe GO qualify for immunosuppression: weekly pulses of intravenous methylprednisolone for 12 weeks are recommended. However, because of disappointing response rates to prednisolone, alternative treatments with similar efficacy but less side effects would be welcome, not only in patients in whom steroids are contraindicated.
A number of studies, have demonstrated that octreotide and lanreotide do not improve or marginally improve eye changes as compared to placebo despite the fact the orbital fibroblast expresses the somatostatin receptor. The cause of these disappointing results could well be the low affinity of octreotide and lanreotide for all somatostatin receptors except subtype sst2, whereas in GO a clear up regulation of sst1 and sst5 on OF has been observed.
Pasireotide (SOM230) indeed has a greater inhibitory effect on in vitro proliferation of orbital fibroblasts than octreotide, and both pasireotide and octreotide inhibit human lymphocyte proliferation albeit acting at different concentrations.
Result of a recent trial that we have performed showed disappointing results when moderate to severe GO patients were treated with intravenous prednisolone with improvement of a predefined response criterium in only ~50% of cases. Previous studies showed higher response rates, which may have been due to the fact that in these early studies patients with more severe GO were included. However, the response to intravenous prednisolone underscores the need of additional therapies.

Study objective

Therefore, we aim to investigate in a pilot trial the effect of SOM230 on predefined endpoints in patients with moderate to severe GO whom have

contraindications for prednisolone therapy or decline from prednisolone therapy for other reasons.

Study design

Prospective observational

Intervention

Admnistration of SOM230 (Pasireotide)

Study burden and risks

Patients will receive three times injection with long acting pasireotide 60mg (intramuscularly) and normal evaluation on the outpatient clinic will ensue. Mild hyperglycemia can be expected and will be monitored.

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

-moderate * severe GO
-corticosteroids contraindicated due to diabetes mellitus (see below), severe osteoporosis, heart failure, psychosis, infectious diseases or other clinical relevant comorbidities
-corticosteroids refused by patients
-age > 18

Exclusion criteria

-inability/refusal to give informed consent
-pregnancy
-GO (dysthyroid optical neuropathy) necessitating high dose steroids or acute decompression
-abnormal thyroid function (defined as TSH >4.0 mU/l or FT4 <10 or >21 pmol/l)
-pregnancy
-drug abuse and smoking.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Signifor
Generic name:	Pasireotide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	30-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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□000435□27-NL
CCMO	NL43961.018.13