SOM230 Graves Orbitopathy pilot trial.

Gepubliceerd: 25-01-2013 Laatst bijgewerkt: 18-08-2022

In this protocol we hypothesize that treatment of patients with moderate to severe Graves Orbitopathy with SOM230 when corticosteroids are contraindicated or unwanted, is beneficial.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26944

Bron
Nationaal Trial Register

Verkorte titel
SOMGO-1

Aandoening

Graves Orbitopathy

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: Academic Medical Center Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

A validated overall ophthalmic/endocrine assessment at the CTEC with predefined criteria for success, no change and worsening of GO at 0, 4, 8 and 12 weeks.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

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.

Doel van het onderzoek

In this protocol we hypothesize that treatment of patients with moderate to severe Graves Orbitopathy with SOM230 when corticosteroids are contraindicated or unwanted, is beneficial.

Onderzoeksopzet

Monthly during 12 weeks (i.e. three dosages).

Onderzoeksproduct en/of interventie

After screening and inclusion, patients will be treated with SOM230 long acting (intramuscular, 60 mgr once monthly) during 12 weeks (i.e. three dosages).

Contactpersonen

Publiek

Academic Medical Center (AMC)
Department of Endocrinology & Metabolism, F5-162
P.O. Box 22660
M.R. Soeters
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5669111

Wetenschappelijk

Academic Medical Center (AMC)
Department of Endocrinology & Metabolism, F5-162
P.O. Box 22660
M.R. Soeters
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5669111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Moderate – severe GO;

2. Corticosteroids contraindicated due to diabetes mellitus, severe osteoporosis, heart failure, psychosis, infectious diseases or other clinical relevant comorbidities;

3. Corticosteroids refused by patients;

4. Age > 18.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Inability/refusal to give informed consent;

2. Pregnancy;

3. GO (dysthyroid optical neuropathy) necessitating high dose steroids or acute decompression;

4. Abnormal thyroid function (defined as TSH >4.0 mU/l or FT4 <10 or >21 pmol/l);

5. Pregnancy;

6. Drug abuse and smoking.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2013
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL3631
NTR-old	NTR3819
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
Optimal management of Graves orbitopathy: a multidisciplinary approach. Soeters MR, van Zeijl CJJ, Boelen A, Kloos R, Saeed P, Vriesendorp TM, et al. The Netherlands journal of medicine. 69(7):302–8.
Efficacy and safety of three different cumulative doses of intravenous methylprednisolone for moderate to severe and active Graves' orbitopathy. Bartalena L, Krassas GE, Wiersinga W, Marcocci C, Salvi M, Daumerie C, Bournaud C, Stahl M, Sassi L, Veronesi G, Azzolini C, Boboridis KG, Mourits MP, Soeters MR, Baldeschi L, Nardi M, Currò N, Boschi A, Bernard M, von Arx G; European Group on Graves' Orbitopathy. J Clin Endocrinol Metab. 2012 Dec;97(12):4454-63.