Stepwise medical treatment of Cushing's disease

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

Samenvatting

ID

NL-OMON20587

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Hypercortisolism due to Cushing's disease

Ondersteuning

Primaire sponsor: Erasmus MC
Dpt. of Internal Medicine, Endocrine Section
Rotterdam
The Netherlands
Overige ondersteuning: Novartis Pharma BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Achievement of normocortisolism

Toelichting onderzoek

Achtergrond van het onderzoek

In this trial patients with Cushing's disease will be treated medically using a stepwise approach with respectively SOM230, cabergoline and ketoconazole.

Doel van het onderzoek

Currently, no effective, non-toxic medical therapy is available for Cushing's disease. Corticotroph adenomas express both somatostatin receptor subtype 5 and dopamine receptors. SOM230 is a new somatostatin analog which binds to 4 of 5 somatostatin receptor subtypes. In vitro studies show that somatostatin analogs and dopamine agonists may potentiate each others effects. Dopamine agonists are also effective in a subset of patients with Cushing's disease. Finally, ketoconazole has apart from its adrenolytic effects, inhibitory effects on ACTH secretion by and cell growth of corticotroph tumor cells which are potentiated by SOM230. By combining these partially independent medical therapies which act through differential mechanisms, we aim at maximizing the number of patients with Cushing’s disease in whom normalization of cortisol production can be achieved.

Onderzoeksopzet

Total study duration is 80 days, evaluation of patients will be performed at day 10, day 26, day 54 and day 80.

Onderzoeksproduct en/of interventie

Patients with Cushing's disease will be treated medically by the following stepwise approach:

- Patients will start with SOM230 (sc.), if this is not effective cabergoline (p.o.) will be added in an increasing dosage, finally when hypercortisolism persists, ketoconazole (p.o.) is added.

Total study duration is 80 days.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Both naïve patients with Cushing’s disease and patients with residual hypercortisolism after recent transsphenoidal adenomectomy are eligible for enrolment.

2. Finally, patients with recurrent Cushing’s disease can also be included.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with poorly controlled diabetes mellitus indicated by a HbA1c % > 8.5 %.

2. Patients with a disturbed liver function indicated by serum bilirubin, ALAT, ASAT or alkaline phosphatase levels > 2.5 x ULN.

3. Patients with renal insufficiency indicated by serum creatinine levels > 2.0 x ULN

4. Patients who are already treated with cortisol lowering therapy can only be included after a wash-out period of 4 weeks followed by re-assessment for hypercortisolism

5. Patients with symptomatic cholelithiasis.

6. Patients with a history of pituitary irradiation.

7. Pregnant patients or patients who desire to become pregnant during the study period.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2007
Aantal proefpersonen:	16
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-07-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 30660
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1322
NTR-old	NTR1379
CCMO	NL13656.078.07
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON30660

Resultaten

Samenvatting resultaten
N/A