Stepwise medical treatment of Cushing's disease

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20587

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Hypercortisolism due to Cushing's disease

Sponsors and support

Primary sponsor: Erasmus MC
Dpt. of Internal Medicine, Endocrine Section
Rotterdam
The Netherlands
Source(s) of monetary or material Support: Novartis Pharma BV

Intervention

Outcome measures

Primary outcome

- Achievement of normocortisolism

Secondary outcome

- Improvement of clinical symptoms of Cushing's disease

- Quality of life

- Glucose tolerance

- Pituitary adenoma size

- Bone metabolism (bone mineral density, bone formative and resorptive markers)

- Hemostasis

Study description

Background summary

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

Study objective

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.

Study design

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

Intervention

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.

Contacts

Public
Erasmus MC
Department of Internal Medicine
Endocrine Section
R.A. Feelders
's Gravendijkwal 230
Rotterdam 3015 EC
The Netherlands
+31 (0)10 7040704
Scientific
Erasmus MC
Department of Internal Medicine
Endocrine Section
R.A. Feelders
's Gravendijkwal 230
Rotterdam 3015 EC
The Netherlands
+31 (0)10 7040704

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2007
Enrollment:	16
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-07-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 30660
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
N/A