An open-label, multi-center, expanded access study of parireotide s.c. in patients with Cushing's disease (CSOM230B2406) (SEASCAPE)

Published: 20-12-2011
Last updated: 01-05-2024

Primary objective: Safety.Secondary objective: Efficacy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Interventional

Summary

ID

NL-OMON39474

Source
ToetsingOnline

Brief title
CSOM230B2406 (SEASCAPE)

Condition

- Hypothalamus and pituitary gland disorders

Synonym
Cushing's disease

Research involving
Human

Sponsors and support

Primary sponsor: Novartis Pharma BV
Source(s) of monetary or material Support: Novartis Pharma BV

Intervention

Keyword: Cushing, Pasireotide, SOM230

Outcome measures

Primary outcome

Adverse events.

Secondary outcome

• To document the efficacy of pasireotide s.c. in normalizing UFC at Week 12

and 24,

separately,

• To document the efficacy of pasireotide s.c. in achieving at least 50%

reduction of UFC from

baseline at Week 12 and 24, separately,

• To document the changes in clinical signs and symptoms,

• To document the changes in patient-reported outcome questionnaires

(CushingQoL and

WPAI-GH),

• To document the effects of pasireotide s.c. on the GH/IGF-I axis.

Study description

Background summary

The trial is planned as an Expanded Access study to provide access and to further document
the safety and the efficacy of pasireotide in patients affected by Cushing*s disease. While
regulatory approval is sought, there are no means available for patients with Cushing*s disease

to receive pasireotide outside of a clinical trial. Patients with post-surgery active disease or
patients who recur after surgery and de novo patients that are not candidates to surgery do not
have an access path to this new agent. Implementation of an Expanded Access Program will
allow access to pasireotide for patients with Cushing*s disease.
Pasireotide is an injectable somatostatin analogue.
The rationale for this study is to give patients with Cushing*s disease access to pasireotide s.c.
as no medical treatment for Cushing*s disease is approved. Thus, a single arm, open label
design is justified in this context.

Study objective

Primary objective: Safety.
Secondary objective: Efficacy.

Study design

Open-label non-comparative phase III 6900 µg bid.
Treatment up to 31-12-2013 or until product is commercially available (whatever comes first). In case product is not yet commencially available in NL on 31-12-2013, the sponsor will arrange continuation of treatment
300 patient (approx. 4 in NL).

Intervention

Treatment with pasireotide s.c.

Study burden and risks

Risks: Adverse effects of study medication. If applicable: (minor) risks/inconveniences of CRH stimulation test.
Burden:
Based on 1 year treatment:
15 visitsin approx. 1 year.
Females are not permitted to removed body hair in the 3 weeks prior to a visit.
14x physical examination.
13x blood tests (approx. 20 ml/visit, fasting). Screening for hepatitis B-C.
10x 24 h urine collection.
3x pregnancy test.
14x ECG.
5x echo gall bladder.
7x completion of 2 questionnaires (qulaity of life and work productivity).

If not performed yet: CRH stimulation test.
Optional: 2x cortisol levels in saliva, assessment of tumor sample removed during prior surgery.

Contacts

Public
Novartis Pharma BV

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NL
Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. male or female patients aged 18 years or above
2. patients with confirmed diagnosis of Cushing's disease as evidenced by:
* Mean urninary free cortisol of three 24-hour urine samples collected during the 3-week screening period above the upper limit of the laboratory non range
* morning plasma ACTH within the normal or above normal range
* either MRI confirmation of pituitary adenoma (greater than or equal to 0.6 cm), or inferior petrosal sinus gradient >3 after CRH stimulation (if IPSS had previously

been performed without CRH, a central to peripheral prestimulation gradient > 2 is required. If IPSS had not previously been performed, IPSS with CRH stimulation is required).
3. Patients with de novo Cushing*s disease must not be considered as candidates for pituitary surgery
4. Karnofsky performance status >60
5. For patients on previous medical treatment for Cushing*s disease the following washout periods must be completed before screening assessments are performed (see protocol section 5.2, item 6 for details).

Exclusion criteria

1. Radiotherapy of the pituitary <4 weeks before screening or patient who has not recovered from side effects
2. Patients with compression of the optic chiasm causing acute clinically significant visual field defect
3. Patients with Cushing*s syndrome due to ectopic ACTH secretion
4. Patients with hypercortisolism secondary to adrenal tumors or nodular (primary) bilateral adrenal hyperplasia
5. Patients who have a known inherited syndrome as the cause for hormone over secretion
6. Patients with a diagnosis of glucocorticoid-remedial aldosteronism (GRA)
7. Patients who have undergone major surgery within 1 month prior to screening
8. Patients with known gallbladder or bile duct disease, acute or chronic pancreatitis (see protocol page 26 for exceptions)
9. Diabetic patients whose blood glucose is poorly controlled as evidenced by HbA1C >8%
10. Patients who have clinically significant impairment in cardiovascular function or are at risk thereof (see protocol for details)
11. Female patients who are pregnant or lactating, or are of childbearing potential and not practicing a medically acceptable method of birth control.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-05-2012
Enrollment:	2
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Signifor
Generic name:	Pasireotide

Ethics review

Approved WMO Date:	20-12-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	24-04-2012
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	31-07-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	07-08-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	10-09-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO	

Date:	28-01-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	29-01-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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
Other	clinicaltrials.gov; NCT01374906
EudraCT	EUCTR2010-024165-44-NL
CCMO	NL38992.044.11