An open-label, multi-center, roll-over study to assess long term safety in patients with endogenous Cushing*s syndrome who have completed a prior Novartis-sponsored osilodrostat (LCI699) study and are judged by the investigator to benefit from continued treatment with osilodrostat

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To evaluatie the long term safety of treatment with osilodrostat for patients with Cushing Syndrome. In addition to evaluating the proportion of patients with clinical benefit (as assessed by the investigator) and determening frequency, severity and...

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

Summary

ID

NL-OMON55862

Source
ToetsingOnline

Brief title
CLCI699C2X01B (roll-over)

Condition

- Hypothalamus and pituitary gland disorders

Synonym
Cushing Syndroom, hypercortisolism

Research involving
Human

Sponsors and support

Primary sponsor: Recordati
Source(s) of monetary or material Support: Novartis Pharma B.V.

Intervention

Keyword: Cushing, LCI699, osilodrostat

Outcome measures

Primary outcome

To evaluate long term safety data through frequency and severity of AE/SAE

Secondary outcome

To evaluate clinical benefit as assessed by the investigator. As well as

frequency, severity and summary of relevant safety assessments sucha s

laboratorium evaluation, vital signs, ECG and MRI.

Study description

Background summary

Osilodrostat is also known under the codename LCI699. Osilodrostat is not yet registered for use by the Dutch health authority. Physicians can not yet use this drug to treat patients with Cushing syndrome. Research is needed to obtain information on the safety and effectiveness of the use of osilodrostat in the treatment of patients with Cushing syndrome.

Study objective

To evaluatie the long term safety of treatment with osilodrostat for patients with Cushing Syndrome. In addition to evaluating the proportion of patients with clinical benefit (as assessed by the investigator) and determening

frequency, severity and summary of relevant safety assessments.

Study design

This is a multi-center, open label phase IIb study to evaluate the long-term safety of osilodrostat in subjects receiving osilodrostat in a Global Novartis-sponsored study which has fulfilled its requirements for the primary objective, and who are judged by their parent study Investigator as benefiting from continued treatment with osilodrostat..There will be no screening period for this study. Eligible subjects can start their treatment with osilodrostat as soon as they are enrolled in the study. The first study visit will be scheduled at the time of the last study visit for the parent study.

Intervention

Use of osilodrostat, and clinic visits and study assessments associated with that.

Study burden and risks

The risks are those associated with the use of osilodrostat, the possible side-effects or adverse events of the drug. The burden consist of the quarterly visits of the patient to the clinic to assess side-effects and continued clinical benefit as well as the study assessments conducted during these visits.

Contacts

Public
Recordati

Lindenstrasse 8
NA NA
CH
Scientific
Recordati

Lindenstrasse 8
NA NA
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Patient is currently participating in a Global Recordati-sponsored study receiving
osilodrostat for any type of endogenous CS and has fulfilled all the requirements in the parent study.
2. Patient is currently benefiting from treatment with osilodrostat, as determined
by the Investigator.
3. Patient has demonstrated compliance, as assessed by the Investigator, with the parent study protocol requirements.
4. Patient is willing and able to comply with scheduled visits and treatment plans.
5. Written informed consent/adolescent assent obtained prior to enrolling into the
roll-over study.

Exclusion criteria

1. Patient has been permanently discontinued from osilodrostat study treatment in a parent Novartis-sponsor study.
2. Patients who are receiving osilodrostat in combination with unapproved or experimental treatments for any type of endogenous CS.
3. Pregnant or nursing (lactating) women, where pregnancy is defined as the state of a female after conception and until the termination of gestation, confirmed by a positive hCG laboratory evaluation.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-11-2019
Enrollment:	2
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Osilodrostat
Generic name:	-

Ethics review

Approved WMO

Date:	31-07-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	14-11-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	21-04-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-05-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-07-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-09-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-11-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-03-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-07-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-06-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	19-07-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-08-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-08-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-10-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2017□002840□34-NL

Register	ID
ClinicalTrials.gov	NCT03606408
CCMO	NL69125.078.19