An open-label phase IIIb study of riociguat in patients with in-operable CTEPH, or recurrent or persisting PH after surgical treatment who are not satisfactorily treated and cannot participate in any other CTEPH trial

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Objectives of the study are to assess safety, tolerability and clinical effects of riociguat and provide access to inoperable patients for a condition (CTEPH) with unmet medical need.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pulmonary vascular disorders
Study type	Interventional

Summary

ID

NL-OMON38503

Source
ToetsingOnline

Brief title
CTEPH EAS

Condition

- Pulmonary vascular disorders

Synonym
- Chronic thromboembolic pulmonary hypertension (Dana Point classification class 4) ; High pressure in the arteries of the lungs due to blood clotting and structural changes

Research involving

Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: Bayer Healthcare AG

Intervention

Keyword: Chronic thromboembolic pulmonary hypertension

Outcome measures

Primary outcome

There are no primary variables. Within this open-label long-term surveillance

study safety and tolerability as well as clinical effects will be measured.

Secondary outcome

NA

Study description

Background summary

Chronic thromboembolic pulmonary hypertension (CTEPH) is a chronic disease with high mortality. Surgery (PEA) is treatment of choice but cannot be done in all patients. These inoperable patients require drugs which are not available (approved). The study will
collect more data for riociguat in CTEPH.

Study objective

Objectives of the study are to assess safety, tolerability and clinical effects of riociguat and provide access to inoperable patients for a condition (CTEPH) with unmet medical need.

Study design

The study will be conducted as an open-label, uncontrolled long-term surveillance study to assess safety, tolerability, and clinical effects while providing early access of riociguat to patients with inoperable CTEPH, or

recurrent or persisting PH after surgical treatment that are not satisfactorily treated and cannot participate in any other CTEPH trial.

Intervention

In the dose titration, the starting dose will be 1 mg riociguat tid. The individual riociguat dose will be titrated every 2 weeks according to the peripheral systolic blood pressure (SBP) and patient*s well-being measured before intake of the next morning dose. At each Titration Visit (with the exemption of Week 0 (Visit 1) the investigator needs to decide, based on the patient*s systolic blood pressure, whether the study medication dose should be modified.
The investigators will apply the following blood pressure based titration rules for their dose decision:
The individual study medication dose of the next titration step will be determined every 2 weeks according to patient*s well-being and the peripheral SBP measured and at trough before intake of the morning dose under consideration of the following algorithm (= individual dose titration scheme):
* If trough SBP * 95 mmHg, increase dose (+0.5 mg tid)
* If trough SBP 90 - 94 mmHg, maintain dose
* If trough SBP <90 mmHg without symptoms of hypotension, reduce dose (-0.5 mg tid)
* If any SBP <90 mmHg with clinical symptoms of hypotension such as dizziness or presyncope, stop study treatment; restart after 24 hours with reduced dose (-0.5 mg tid).
The individual dose titration scheme is based on the patient*s systolic blood pressure and patient*s well-being. It is allowed in case of study medication side effects, to suspend a foreseen up-titration step and to maintain the dose.
In the main study phase, riociguat should be continued at the optimal dose as determined at the end of the titration phase. Dose reductions or stop of study medication for safety reasons are allowed at any time. Increases or re-increases in 0.5 mg steps (maximum dose 2.5 mg) are possible at the investigator*s discretion weighing the benefit with potential risks implied, e.g. hypotension.

Study burden and risks

The burden of participation will be to meet the frequent and time-consuming visits for the study. The risks involved are mainly those related to vasodilatory effects of riociguat (like hypotension) but benefits include improvement in pulmonary hemodynamics and functional capacity (eg exercise tolerance/6 MWD) as already proven with riociguat in a recent trial (CHEST).
The benefit-risk assessment for riociguat has been shown to be positive.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Male and female patients with CTEPH either inoperable or with persistent or recurrent PH after surgery.

Exclusion criteria

- All types of pulmonary hypertension other than Dana Point Classification Group 4
- Operable patients listed for PEA (Pulmonary Endarterectomy)

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):	04-09-2013
Enrollment:	23
Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	riociguat

Ethics review

Approved WMO Date:	21-02-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	28-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2012-002104-40-NL
CCMO	NL43200.029.13