Long-term extension, multi-centre, multi-national study to evaluate the safety and tolerability of oral BAY 63-2521 (1 mg, 1.5 mg, 2 mg, or 2.5 mg tid) in patients with symptomatic Pulmonary Arterial Hypertension (PAH).

Published: 24-11-2008
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON35533

Source
ToetsingOnline

Brief title
PATENT-2

Condition

- Heart failures
- Pulmonary vascular disorders

Synonym
Pulmonary hypertension / increased blood pressure in the lungs

Research involving
Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: Bayer Schering Pharma

Intervention

Keyword: (PAH), 1. Pulmonary Arterial Hypertension, 2. Systolic bloodpressure

Outcome measures

Primary outcome

Primary endpoints are safety and tolerability of a long-term treatment with BAY

63-2521.

Secondary outcome

Secundary endpoints are:

- Change from baseline in 6 MWD test

- Change from baseline in NT-pro BNP

- Change from baseline in WHO functional class

- Time To Clinical Worsening

- Change from baseline in Borg CR10 Score (measured at the end of the 6MWD

Test)

- Change from baseline in EQ-5D questionnaire

- Change from baseline in LPH questionnaire

- Change in use of healthcare resources

Study description

Background summary

Pulmonary Arterial Hypertension (PAH) is a severe disease with a high mortality. Although several drugs have been approved for the treatment of PAH in the recent past, there is still a high medical need for new treatments.

Although the experiences with BAY 63 2521 with respect to the treatment of PAH are limited, in the light of the severity of the underlying disease it is justified to offer all patients who participated in the PATENT-1 trial a long-term treatment with BAY 63 2521 (until commercially available).

Study objective

BAY 63 2521 is a stimulator of the soluble guanylate cyclase (sGC) and is intended for the treatment of cardiovascular diseases, especially pulmonary hypertension (PH).

To assess the long-term safety and tolerability of BAY 63 2521 in the treatment of naive patients and patients pretreated with an Endothelin Receptor Antagonist or a Prostacyclin Analogue with symptomatic Pulmonary Arterial Hypertension (PAH).

Study design

Multicentre, multinational, open label one arm study in patients with symptomatic PAH.

Intervention

Patients from the Placebo Arm and from the BAY 63 2521 1.5 mg Dose Arm of PATENT 1 trial will be up-titrated to maximum of 2.5 mg. Patients from the 2.5 mg BAY 63-2521 arm will maintain the same dose in the PATENT-2 trial.

Study burden and risks

The treatment period is set up as follow:
1. Treatment Phase
a. Titration phase: 8 weeks
b. Main-study phase: Duration until BAY 63-2521 receives official approval and will be commercially available.
2. Safety follow up phase: 30 days

Incase patients participate until day 84 + the safety follow-up period:

7 hospital visits, 1 time hospitalisation for day and night, study medication tid, possible side-effectd due to study medication, blood pressure (15x), heart rate (15x), WHO functional class (4x), 6 MWD (4x), Borg CR10 Scale (4X), lab blood sampling (4x), PK blood sampling (2x), ECG (6x), EQ-5D questionairre (1x), LPH questionairre (1x).

From day 84, every 3 months the following procedured will be repeated: Study medication tid, possible side-effects due to study medication, physical examination, blood pressure, heart rate, blood gas analysis, WHO functional class , 6 MWD, Borg CR10 Scale, lab blood sampling, PK blood sampling, ECG, pregnancy test if appicable, EQ-5D questionairre, LPH questionairre.

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

1) Signed and dated informed consent
2) Patients who have completed 12 weeks of treatment in the PATENT 1 trial.

Exclusion criteria

See page 14 of the protocol _ Paragraph 4.2.2

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):	09-03-2009
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	NVT
Generic name:	Riociguat

Ethics review

Approved WMO

Date:	24-11-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-02-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-05-2009
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-07-2009
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-04-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-05-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-03-2011
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	EUCTR2008-003610-94-NL
ClinicalTrials.gov	NCT00863681
CCMO	NL25453.029.08