Randomized, double-blind, placebo-controlled, multi-centre, multi-national study to evaluate the efficacy and safety 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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BAY 63 2521 is a direct stimulator of the soluble Guanylate Cyclase (sGC) and is intended for the treatment of cardiovascular diseases, especially Pulmonary Hypertension (PH).To assess the efficacy and safety of oral BAY 63 2521 in the treatment of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON35306

Source
ToetsingOnline

Brief title
PATENT-1 Study

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

The primary endpoint is change from baseline in 6 Minute Walking Distance

(6MWD) after 12 weeks.

Secondary outcome

Secondary efficacy endpoints are:

- Change from Baseline in Pulmonary Vascular Resistance (PVR) after 12 weeks

- Change from baseline in NT-pro BNP after 12 weeks

- Change from baseline in WHO functional class after 12 weeks

- Time To Clinical Worsening

- Change from baseline in Borg CR 10 Scale (measured at the end of the 6MWD

Test) after 12 weeks

- Change from baseline in EQ-5D questionnaire after 12 weeks

- Change from baseline in LPH questionnaire after 12 weeks

- Change in use of healthcare resources after 12 weeks

Safety Variables:

- Treatment emergent adverse events

- Treatment emergent serious adverse events

- Laboratory parameters

- ECG

- Heart rate

- Blood pressure

- Blood gases

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.

Study objective

BAY 63 2521 is a direct stimulator of the soluble Guanylate Cyclase (sGC) and is intended for the treatment of cardiovascular diseases, especially Pulmonary Hypertension (PH).

To assess the efficacy and safety of oral BAY 63 2521 in the treatment of naïve patients and patients pretreated with an Endothelin Receptor Antagonist or a Prostacycline Analogue with symptomatic Pulmonary Arterial Hypertension (PAH).

Study design

Randomized, double-blind, placebo-controlled, multi-centre, multi-national study to evaluate the efficacy and safety of oral BAY 63-2521 in patients with symptomatic PAH

Intervention

A three arm study (4:2:1)

1) 264 patients will receive a BAY 63 2521 dose between 1 mg and 2.5 mg tid determined based on an individual dose titration scheme
2) 132 patients will receive placebo tablets tid
3) 66 patients will be up-titrated to 1.5 mg BAY 63 2521 tid

Study burden and risks

The treatment period is set up as follow:
1. Pre-treatment phase: approximately 2 weeks
2. Treatment phase: 12 weeks
a. Titration phase: 8 weeks
b. Main phase 4 weeks
3. Safety Follow Up phase: 30 days

Incase the patient participates the entire treatment period:
8 hospital visits, 1 x hospitalisation for 1 day/night & 2 x hospitalisation for 1 day (and possibly a night), study medication tid, possible side-effects due to the study medication, physical examination (3x), blood pressure (16x), heart rate (16x), lung function test (1x), blood gas analysis (3x), WHO functional class (6x), 6MWD test (7x), Borg CR 10 Scale (7x), invasive haemodynamic measurement (2x), lab blood sampling (15x), PK blood sampling (6x), ECG (42x; each ECG is performed 3 times with 1 minute interval), pregnancy test if applicable (3x) EQ-5D questionnaire (3x), LPH questionnaire (3x) & Pharmacogenetic (1x)

Contacts

Public
Bayer

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NL
Scientific
Bayer

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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) 18 to 80 years of age at Visit 1
3) Male and female patients with symptomatic PAH (Group I / Venice Clinical Classification of PH), a 6MWD test between 150 m and 450 m, a pulmonary vascular resistance (PVR) >300 dyn*sec*cm-5 and a mean pulmonary artery pressure >25 mmHg
4) Treatment naïve patients (with respect to PAH specific medication) and patients pre-treated with an Endothelin Receptor Antagonist or a Prostacycline Analoguea.

Exclusion criteria

See page 18 - 21 of the protocol _ Paragraph 4.2.2

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2009
Enrollment:	10
Type:	Anticipated

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:	14-05-2009
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-07-2009
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:	05-05-2010
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	EUCTR2008-003482-68-NL
ClinicalTrials.gov	NCT00810693
CCMO	NL25452.029.08