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 Chronic Thromboembolic Pulmonary Hypertension (CTEPH).

Published: 24-11-2008
Last updated: 06-05-2024

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

Summary

ID

NL-OMON37288

Source
ToetsingOnline

Brief title
CHEST-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 Healthcare

Intervention

Keyword: (PH), 1. Chronic Thromboembolic, 2. Pulmonary Hypertension, 3. Systolic bloodpressure, Pulmonary Hypertension (CTEPH)

Outcome measures

Primary outcome

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

(6MWD) after 16 weeks.

Secondary outcome

Secondary efficacy endpoints are:

- Change from Baseline in Pulmonary Vascular Resistance (PVR) after 16 weeks

- Change from baseline in NT-pro BNP after 16 weeks

- Change from baseline in WHO functional class after 16 weeks

- Time To Clinical Worsening

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

Test) after 16 weeks

- Change from baseline in EQ-5D questionnaire after 16 weeks

- Change from baseline in LPH questionnaire after 16 weeks

- Change in use of healthcare resources after 16 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

Chronic Thromboembolic Pulmonary Hypertension (CTEPH) is a severe disease with a high mortality. Although pulmonary endarterectomy (PEA) has been proven to be a very effective treatment for CTEPH it cannot be performed in a substantial proportion of patients. Therefore, there is a high need for medical treatments for CTEPH patients that are inoperable or who have a persistent pulmonary hypertension after they underwent PEA.

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 efficacy and safety of oral BAY 63 2521 in patients with inoperable Chronic Thromboembolic Pulmonary Hypertension (CTEPH) or recurrent or persisting pulmonary hypertension after surgical treatment.

Study design

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

Intervention

A two arm study (2:1):

1) 180 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) 90 patients will receive placebo tablets tid

Study burden and risks

The treatment period is set up as follow:
1. Pre-treatment phase: approximately 4 weeks
2. Treatmentphase: 16 weeks
a. Titration phase: 8 weeks
b. Main phase: 8 weeks
3. Safety Follow Up phase: 30 days

Incase the patient participates the entire treatment period:
9 hospital visits, 1 time hospitalisation for day and night & 2 hospitalisations for 1 day (and possibly for a night), study medication tid, possible side-effects due to study medication, Physical examination (3x), blood pressure (16x), heart rate(16x), lung function test (1x), blood gas analysis (3x), WHO functional class (7x), 6 MWD (8x), Borg CR10 Scale (8X), invasive heamodynamic measurement (2x), lab blood sampling (11x), PK blood sampling (7x), ECG (11x), pregnancy test if applicable (3x), EQ-5D questionairre (3x), LPH questionairre (3x).

Contacts

Public
Bayer

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NL
Scientific
Bayer

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NL

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 CTEPH and a 6MWD Test between 150 m and 450 m either defined as:
a) Inoperable due to the consideration of an experienced surgeon, with
pulmonary vascular resistance >300 dyn*sec*cm-5 measured at least 90 days after start of full anticoagulation and mean pulmonary artery
pressure >25 mmHg
b) With persisting or recurrent PH after Pulmonary Endarterectomy
4) Unspecific treatments which may also be used for the treatment of pulmonary hypertension such as oral anticoagulants, diuretics, digitalis, calcium channel
blockers or oxygen supplementation are permitted. ;See page 15 - 17 of the protocol Paragraph 4.2.1

Exclusion criteria

See page 17 - 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):	19-08-2010
Enrollment:	9
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:	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:	15-10-2009
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:	09-12-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-12-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-04-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-06-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-06-2011
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	EUCTR2007-000072-16-NL
ClinicalTrials.gov	NCT00855465
CCMO	NL25450.029.08