A single blind, placebo controlled pilot study to explore the safety and tolerability of a single oral dose of 30 mg BAY 1067197 in patients with chronic heart failure on the background of preexisting beta-blocker therapy

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

Summary

ID

NL-OMON38750

Source ToetsingOnline

Brief title BAY 1067197 in stable HFpatients on standard therapy

Condition

• Heart failures

Synonym congestive heart failure, heart failure

Research involving

Human

Sponsors and support

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

Intervention

Keyword: BAY 1067197, heart failure, safety, tolerability

Outcome measures

Primary outcome

• The primary outcome is the occurrence of AV-Block > I° (under therapy with

BAY1067197 and preexisting β -blocker therapy) up to 48 hours.

Secondary outcome

• Evaluate the safety and tolerability of 1 day treatment with BAY 1067197 in

heart failure patients on top of standard therapy

• To assess the pharmacokinetic profile of a single dose BAY 1067197 in heart

failure patients on standard therapy

- Heart rate; multiple time points up to 24 hours
- Blood pressure; multiple time points up to 24 hours

Study description

Background summary

- BAY 1067197 is the prodrug of the pharmacologically active partial adenosine

A1 agonist BAY 84-3174, which will be developed for the treatment of worsening heart failure (HF).

- HF has grown to epidemic proportions in the western world and worsening HF occurs annually in 30% of NYHA III and IV patients. Despite medical advances in the treatment of HF over the last 2 decades, worsening HF remains a highly fatal disease.

- The selective and highly potent partial adenosine A1 receptor agonist provides a novel approach in the therapy of HF by improvement of heart function via restoration of myocyte energetics and calcium handling.

Study objective

Primary

The objective of the study is to investigate the safety and tolerability of the partial adenosine A1 agonist BAY 1067197 on top of standard therapy in patients with chronic systolic heart failure.

Secundary Pharmacodynamische en hemodynamische response to a single dose of BAY 1067197

Study design

Placebo-controlled, single dose administration, single blind, single center design

Intervention

Single dose, 30 mg oral BAY 1067197 or placebo

Study burden and risks

Burden consists primarily of hospital stay and repeated blood collections and clinical assessments. No invasive additional investigations.

Contacts

Public Bayer

Kaiser-Wilhelm-Allee 10 Leverkusen 51368 DE **Scientific** Bayer

Kaiser-Wilhelm-Allee 10 Leverkusen 51368 DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

•Stable systolic heart failure (heart failure with reduced ejection fraction, HFrEF; NYHA I-III) in sinus rhythm with a documented EF <=45% within the last 3 months;•Stable standard HF therapy including intermediate to high dose β -blocker with either >= 95 mg metoprolol succinate (controlled release tablet), >= 5mg Bisoprolol (IR-tablet) or >=5mg Nebivolol (IR tablet) for at least 4 weeks. Additional intake of angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers and optional aldosterone-receptor antagonists, diuretics or digitalis is allowed; • Men or confirmed postmenopausal women (defined as being amenorrheic for longer than 2 years with an appropriate clinical profile, e.g. age appropriate and a history of vasomotor symptoms) or women without childbearing potential based on surgical treatment such as bilateral tubal ligation, bilateral ovarectomy or hysterectomy (documented by medical report verification). Men enrolled in this study must agree to use adequate barrier birth control measures during the treatment period of the study and for 12 weeks after receiving the investigational medicinal product (IMP); • Male patients must agree not to act as sperm donor for 12 weeks after dosing; • Age: 18 to 75 years (inclusive) at the first screening visit; • Ethnicity: White; • Body mass index (BMI): above/equal 18.0 and below/equal 29.9 kg/m²

Exclusion criteria

•Biventricular pacing/active CRT device; •Dependency on pacemaker or ICD device with pacemaker dependency (a paced ventricular rhythm > 5% of heart activity); •A history of relevant diseases of vital organs other than the heart, of the central nervous system or other organs; •Known hypersensitivity to the study preparations (active substances or excipients of

the preparations) or to any other β -blocker; •Current or history of AV-Block > I°; •Unstable condition, indicated by requirement of IV drug (diuretic, inotrope, etc.) or NYHA IV; •Acute Coronary Syndrome (defined as unstable angina [UA], non-ST elevation myocardial infarction [NSTEMI], ST elevation myocardial infarction [STEMI]) within 3 months prior to first study drug administration; •History of asthma or COPD >= GOLD II and/or allergic asthma

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):	16-12-2014
Enrollment:	10
Туре:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	BAY 1067197 HCL 10 mg tablet
Generic name:	BAY 1067197 HCL 10 mg tablet

Ethics review

Approved WMO	
Date:	15-08-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	

Date:	04-11-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-12-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-12-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-05-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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 EudraCT ClinicalTrials.gov CCMO ID EUCTR2013-001287-34-NL NCT01945606 NL45286.042.13