# 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
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DE
**Scientific**
Bayer

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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 |
| Type: | Actual |

## Medical products/devices used

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

# Ethics review

Approved WMO

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

Approved WMO

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