PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

A Double Blinded, Placebo Controlled, Study to Investigate the Safety, Tolerability, Pharmacokinetics and Acute Cardiovascular Responses of a 7 Day Oral Treatment With the Partial Adenosine A1 Receptor Agonist BAY1067197 in Patients With Chronic Systolic Heart Failure: the PARSiFAL-pilot Study.

Trial Acronym

PARSiFAL

URL of the trial

[---]*

Brief Summary in Lay Language

This is a study to investigate the safety, tolerability and early effects on cardiac function of the partial A1 agonist BAY1067197 in patients with chronic heart failure.
BAY1067197 will be applied once daily over 7 days in addition to standard therapy including a beta-blocker. The aim of the study is to assess if a 7 day treatment with BAY1067197 is well tolerated when given on top of standard therapy for heart failure. Furthermore, the study aims to assess if cardiac function improves in the early course of therapy.

Brief Summary in Scientific Language

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Organizational Data

- DRKS-ID: **DRKS00005890**
- Date of Registration in DRKS: **2015/03/04**
- Date of Registration in Partner Registry or other Primary Registry: **2014/01/17**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

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Ethics Approval/Approval of the Ethics Committee: **[---]***
(leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2013-002522-23**
- Primary Registry-ID: **NCT02040233 (ClinicalTrials.gov)**
- Sponsor-ID: **16782 (Bayer)**
- Other Secondary-ID: **2013-002522-23**

Health condition or Problem studied

- Free text: **Heart Failure**
- ICD10: **I50 - Heart failure**

Interventions/Observational Groups

- Arm 1: **Drug: BAY1067197 (10 mg)**
- Arm 2: **Drug: BAY1067197**
- Arm 3: **Drug: Placebo (10 mg)**
- Arm 4: **Drug: Placebo**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, caregiver, investigator/therapist**
- Control: **Placebo**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **patient/subject, caregiver, investigator/therapist**

Control: **Placebo**

- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Number of participants with adverse events characterised by change in heart rate as a measure of safety; time frame: After 7 day treatment
- Number of participants with adverse events characterized by change in blood pressure as a measure of safety; time frame: After 7 day treatment
- Number of participants with adverse events characterised by change in the incidence of higher degree AV-block > I° as a measure of safety; time frame: After 7 day tratment and day 28
- Changes in left ventricular ejection fraction; time frame: Baseline to day 7
- Plasma Concentration of BAY 1067197 characterized by Cmax; time frame: 1 st day of study; (maximum drug observed concentration)
- Plasma concentration of BAY 1067197 characterized by Cmax/D; time frame: 1 st day of study; (maximum drug observed concentration divided by Dose)
- Plasma concentration of BAY 1067197 by AUCτ; time frame: 1 st day of study; (AUC for the actual dose interval, If applicable ,the day of AUCτ is specified as AUCτ (day n)
- Plasma concentration of BAY 1067197 by AUCτ /D; time frame: 1 st day of study; (AUCτ divided by dose)
- Plasma concentration of BAY 1067197 by Cmax,md; time frame: 7 th day of study; (maximum drug observed concentration after multiple dose administration during a dose interval)
- Plasma concentration of BAY 1067197 by Cmax,md/D; time frame: 7 th day of study; (Cmax,md divided by dose)
- Plasma concentration of BAY 1067197 by AUCτmd; time frame: 7 th day of study; (AUC for the any dose interval, after multiple dose)
- Plasma concentration of BAY 1067197 by AUCτmd/D; time frame: 7 th day of study; AUCτmd divided by dose)

Secondary Outcome

- Wall motion scores and wall motion score index; time frame: Baseline to day 7

Countries of recruitment

- DE **Germany**
- IT **Italy**
- NL **Netherlands**
- PL **Poland**

Locations of Recruitment

- **Berlin**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2014/01/31**
- Target Sample Size: **32**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

- Clinical diagnosis of chronic systolic heart failure of ischemic or non-ischemic etiology:(New York Heart Association)NYHA class I-III and treatment with standard pharmacological therapy for the treatment of systolic heart failure including β-blocker ≥ 4 weeks prior to randomization

- Left ventricular ejection fraction ≤ 40%: by any imaging technique within the last 3 months will be accepted for screening purposes but will be verified by baseline CMR(Cardiac Magnetic Resonance Tomography)

- Sinus rhythm for at least 4 weeks prior to randomization

- No planned changes to heart failure related drug therapy for the duration of study

drug treatment

- Substantial dysfunctional but viable myocardium as demonstrated by the baseline CMR:
Based on a standard 17-segment model (AHA - American Heart Association), 3 or more
segments require demonstration of dysfunction (defined by visible assessment of the
performing investigator) and viability (defined as < 25% of segment area with scar
burden - in patients with CAD (Coronary Artery Disease) or no (i.e. zero) scar burden
in patients without CAD [idiopathic CM patient])

- Men or confirmed postmenopausal women or women without childbearing potential.

- Age: 18 to 75 years (inclusive) at the first screening visit.

- Body Mass Index (BMI) :above /equal 18.0 and below/equal 34.9kg/m²

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Exclusion criteria

- Atrial fibrillation / atrial flutter within the last 4 weeks prior to randomization
or currently persistent/permanent atrial fibrillation / atrial flutter

- Primary valvular disease (severe valvular disease) with planned valve repair or
replacement

- Non-idiopathic non-ischemic causes for cardiomyopathy (constrictive, restrictive, or
hypertrophic cardiomyopathy; acute myocarditis)

- Listing for heart transplantation and/or anticipated/implanted ventricular assist
device Clinically relevant ventricular arrhythmias within the last 2 months
(sustained ventricular tachycardia, ventricular flutter or fibrillation), based on
either medical history or ICD-testing results (if applicable)

- Unstable cardiac condition, indicated by requirement of IV drug (diuretic, inotrope,
etc.) or NYHA IV within 4 weeks prior to randomization

- Coronary revascularization within 4 weeks prior to randomization or if revascularization is anticipated or needed

- Current permanent or intermittent AV-Block > I° or history of AV-Block > I° within
six months before enrollment

- PR duration ≥ 300 ms

- Acute Coronary Syndrome (defined as unstable angina [UA], non-ST

elevation myocardial infarction [NSTEMI], ST elevation myocardial infarction [STEMI]) within 2 months prior to randomization

- Subjects with untreated hyperthyreoidism or hypothyreosidism and non-stable thyroid function (intake of stable thyroid hormone substitution allowed)

Addresses

■ **Primary Sponsor**

Bayer

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Bayer
Bayer Study Director

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Public Queries**

Bayer Clinical Trials Contact

Telephone: **[---]***
Fax: **[---]***
E-mail: **clinical-trials-contact at bayerhealthcare.com**
URL: **[---]***

Sources of Monetary or Material Support

■ **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***

[---]*

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Further trial documents **Click here and search for drug information provided by the FDA.**
- Further trial documents **Click here and search for information on any recalls, market or product safety alerts by the FDA which might have occurred with this product.**

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 1
- Last processed date by ClinicalTrials.gov: 2014/02/23

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*