Prematurely ended-statement

EudraCT Number:	2007-004150-85
Full title of trial:	Cardiac failure with normal ejection fraction: possible role of phosphodiesterase type 5 inhibitors.
Protocol Code:	HINEF: PDE5
Sponsor:	Charité – Unversitätsmedizin Berlin
Sponsor Representative:	PD Dr. med D. Westermann
Investigator:	PD. Dr. C. Tschöpe Charité, Campus Benjamin Franklin Abt. f. Kardiologie und Pulmologie Hindenburgdamm 30, 12203 Berlin **new adress:** Prof. Dr. C. Tschöpe Medizinische Klinik m.S. Kardiologie Campus Virchow-Klinikum Medizinische Klinik m.S. Kardiologie Augustenburger Platz 1, 13353 Berlin carsten.tschoepe@charite.de
Product:	Vardenafil (Levitra/ Bayer Healthcare)
Date of the early Termination:	February 23, 2010
Statement:	On behalf of the sponsor, this is to confirm that above trial never recruited a patient.

Name of Sponsor/ Representative of Sponsor: Charité – Universitätsmedizin Berlin, Hindenburgdamm 30, 12203 Berlin (vertreten durch Prof. Jörg Westermann u. Prof. Dr. Carsten Tschöpe	Individual Study Table Referring to Part of the Dossier Volume: Page:	*(For National Authority Use only)*
Name of Finished Product: Levitra		
Name of Active Ingredient: Vardenafil		

Title of Study: Cardiac failure with normal ejection fraction: possible role of phosphodiesterase type 5 inhibitors.

Name or abbreviated title of the trial:

EudraCT-Number: 2007-004150-85

Sponsor's protocol code number: HINEF: PDE5

Principal Investigators:

Dr. med. D. Westermann
Charité - Universitätsmedizin Berlin
Campus Benjamin Franklin
Abteilung für Kardiologie und Pulmologie,
Hindenburgdamm 30, 12203 Berlin

Prof. Dr. med. Carsten Tschöpe
Charité - Universitätsmedizin Berlin
Campus Virchow-Klinikum
Medizinische Klinik m.S. Kardiologie
Augustenburger Platz 1, 13353 Berlin
carsten.tschoepe@charite.de

Study centre(s): Charité, Campus Benjamin Franklin
Abt. f. Kardiologie und Pulmologie
Hindenburgdamm 30, 12203 Berlin

Investigator: Dr. D. Westermann, Dr. Mario Kasner

Publication (reference): none

Studied period (years):	Phase of development:
The study was suspended during the screening phase before recruiting of the first patient.	

Objectives:

Primary Endpoint: Improvement of cardiac insufficiency symptoms in patients treated additionally with vardenafil (evaluated by 6-minute-walk-test, NYHA class, ergospirometry and the Minnesota Living with Heart Failure Questionnaire).

Secondary Endpoints: Improvement of the diastolic function (evaluated by invasive cardiac catheter and non-invasive echocardiography) as cardiac insufficiency parameter NT-pro-BNP, IL-6 and CRP in patients treated additionally with vardenafil.

Methodology:

4 patients were screened no patients were enrolled.

SYNOPSIS

entsprechend Annex 1 der *Note for guidance on structure and content of clinical study reports* (CPMP/ICH/137/95) - ICH Topic E 3

Number of patients (planned and analysed): To be allocated to trial: n=30 No patients were recruited.
Diagnosis and main criteria for inclusion/exclusion: See study protocol. No patients were recruited.
Randomized IMP treatment was: Not applicable. No patients were recruited.
Test product, dose and mode of administration, batch number: Not applicable. No patients were recruited.
Duration of treatment: Not applicable. No patients were recruited.
Reference therapy, dose and mode of administration, batch number: Not applicable. No patients were recruited.
Criteria for evaluation: Not applicable. No patients were recruited.
Summary - Conclusions Not applicable. No patients were recruited.
Date of the report: 10.12.2021

PRINCIPAL OR COORDINATING INVESTIGATOR(S) SIGNATURE(S)
OR SPONSOR'S RESPONSIBLE MEDICAL OFFICER

STUDY TITLE: Determination of the penetration of antibiotics into epithelial lining fluid during continuous infusion in mechanically ventilated ICU patients: example meropenem

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study

INVESTIGATOR: Prof. Dr. Carsten Tschöpe SIGNATURE(S)
OR SPONSOR'S
RESPONSIBLE
MEDICAL OFFICER

DATE: 21.12.21