Clinical trial results:
Effects of selective serotonin re-uptake inhibition on morbidity, mortality and mood in Depressed Heart Failure patients

Summary

EudraCT number	2007-006609-25
Trial protocol	DE
Global end of trial date	02 September 2014

Results information

Result version number	v1 (current)
This version publication date	04 June 2021
First version publication date	04 June 2021
Summary attachment (see zip file)	MOOD-HF_Synopsis (MOOD-HF_Synopsis_AMG_final1.0_2015-09-01_unterschrieben_geschwaerzt.pdf)

Trial information

Trial identification

Sponsor protocol code	MOOD-HF

Additional study identifiers

ISRCTN number	ISRCTN33128015
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Universität Würzburg
Sponsor organisation address	Sanderring 2, Würzburg, Germany, 97078
Public contact	Deutsches Zentrum für Herzinsuffizi, University Hospital Würzburg, ++49 93120146361, Angermann_C@ukw.de
Scientific contact	Deutsches Zentrum für Herzinsuffizi, University Hospital Würzburg, ++49 93120146361, Angermann_C@ukw.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	01 September 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 September 2014
Global end of trial reached?	Yes
Global end of trial date	02 September 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to investigate the effects of treatment with the SSRI escitalopram compared to placebo on morbidity and mortality in CHF patients with a current episode of major depression

Protection of trial subjects:

Patients were closely monitored with regard to safety during the course of the study, with several secondary endpoints as indicators for safety based on the underlying disease.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 March 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 376
Worldwide total number of subjects	376
EEA total number of subjects	376

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	217
From 65 to 84 years	157
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Between March, 2009, and September, 2014, 372 patients from 16 German trial sites were enrolled to the MOOD-HF trial.

Pre-assignment

Screening details:

Patients were eligible for the trial, if they were >= 18 years of age, had chronic systolic heart failure of any etiology (current NYHA class II-IV and >= one measurement of LVEF <45% within the preceding three months) and had a diagnosis of current major DEP based on the Structured Clinical Interview for DSM-IV (SCID).

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Escitalopram

Arm description:

Cardiological care + escitalopram 10-20 mg/day p.o.

Arm type	Experimental
Investigational medicinal product name	Escitalopram
Investigational medicinal product code	
Other name	Cipralex®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Patients started with a dose of 5 mg once daily and were uptitrated after 3 weeks to 10 mg once daily. After further three weeks patients up to 65 years old were uptitrated to 20 mg/day. Slower up-titration was permitted for tolerability reasons. Twelve weeks after study start the final dosage of study drug had to be reached.

Arm title	Placebo

Arm description:

Cardiological care + placebo 10-20 mg/day p.o.

Arm type	Placebo control

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Escitalopram	Placebo
Started	186	190
Completed	186	190

Baseline characteristics

End points

End points reporting groups

Reporting group title	Escitalopram
Reporting group description:	
Cardiological care + escitalopram 10-20 mg/day p.o.	
Reporting group title	Placebo
Reporting group description:	
Cardiological care + placebo 10-20 mg/day p.o.	

Primary: Effect of selective serotonin re-uptake inhibition on morbidity and mortality in depressed patients with CHF

End point title	Effect of selective serotonin re-uptake inhibition on morbidity and mortality in depressed patients with CHF[1]
End point description:	
End point type	Primary
End point timeframe:	
The primary endpoint is measured by the time to a first clinical event, either death or unplanned hospitalisation, whichever occurs first.	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: For analysis results please see attached pdf or JAMA. 2016 Jun 28;315(24):2683-93. doi: 10.1001/jama.2016.7635

End point values	Escitalopram	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	185[2]	187[3]		
Units: whole	185	187		

Notes:

[2] - One patient discontinued trial participation before starting IMP

[3] - Three patients discontinued trial participation before starting IMP

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
Adverse Event reporting was mandatory from screening until the last visit of a patient.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.0

Frequency threshold for reporting non-serious adverse events: 5 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: For a description and summary of non-serious adverse events please see attached pdf

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 December 2008	- exclusion criteria: 1. moderate and severe dementia (MMSE <18) (moderate) / 2. Thyreotoxicosis (new exclusion criteria) - study medication: start dosis of 10 mg/d is possible according to the recommendation of the consulting psychiatrist - change of 2 stratification features (PHQ-sum score and hospitalization within the past 4 weeks at the time of SCID - a new secondary endpoint (effect of optimized cardiological care) - update of the assessment of patients - change in documentation and reporting of SAE - new trial site
24 September 2009	Addition of two new trial sites (university of Rostock and university of Leipzig) and closing of the trial site Charité Berlin
22 June 2010	Three new trial sites (Universitäres Herzzentrum Hamburg, Medizinische Hochschule Hannover and Universität Magdeburg).
23 February 2011	New investigator (PZ Würzburg)
23 February 2011	Change in contact data at the trial site in Würzburg incl. resulting change in IMPD-label
10 May 2011	- Transfer of patients for SCID stariong at PHQ-9-sum of 9 (up to amendment: 12) - introduction of a new scientific side project (Fe-MOOD) - three new tral sites - deregistration of two trial sites - registration of new investigators at already registered trial sites
12 September 2011	- change in an exclusion criterion - registration of a new trial site (Uniklinikum Regensburg) - registration of new investigators
28 October 2011	- addition of two new exclusion criteria - reduktion of maximum daily dose to 10 mg in patients aged >=65 years - registration and deregistration of trial sites - PI-change in Hamburg - registration and deregistration of investigators - Recalculation of subject number
23 October 2012	- PI-change in Hannover and Lübeck - deregistration of Stuttgart - registration of new investigators - change in contact data of the trial bimetrician
24 May 2013	- PI-change in Lübeck and Marburg - registration of deputy investigators at already registered trial sites (Bad Nauheim, Bonn, Homburg/Saar, Leipzig), die noch nicht als Prüfer bewertet wurden - deregistration of trial sites (Hannover, Mannheim, München and Regensburg)

05 March 2014	- trial duration and definition of the end of trial - reduction of the package size of the study medication starting with the current batch.e - Update of data related to the trial team (contacts, members of the endpoint committee)

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported