Clinical trial results:
GLYcemic Control with EMpagliflozin vs standard of care in patients with type 2 dIAbetes and Heart failure: effects on cardiac remodeling and neurohormonal activation

Summary

EudraCT number	2018-000832-82
Trial protocol	IT
Global end of trial date	07 April 2022

Results information

Result version number	v1 (current)
This version publication date	15 December 2022
First version publication date	15 December 2022
Summary attachment (see zip file)	Final report_2018-000832-82 (Final report_2018-000832-82.pdf)

Trial information

Trial identification

Sponsor protocol code	GLYCEMIA-Heart

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Fondazione Toscana Gabriele Monasterio
Sponsor organisation address	Via g moruzzi, Pisa, Italy,
Public contact	U.O.C. Farmaceutica Ospedaliera, Fondazione Toscana Gabriele Monasterio, +39 0585493507, farmacisti@ftgm.it
Scientific contact	U.O.C. Farmaceutica Ospedaliera, Fondazione Toscana Gabriele Monasterio, +39 0585493507, farmacisti@ftgm.it

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	28 October 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 April 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Test the effects of empagliflozin on neuro-hormonal activation, as exstimated by 1-year variation in NT-proBNP plasma concentrations

Protection of trial subjects:

The study protocol was evaluated and approved by the local Ethics Committee (CEAVNO) and by the Competent Authority, or the Italian Medicines Agency (AIFA). The study was performed in accordance with the Helsinki Declaration. The willingness of each individual patient to participate in the study was respected and informed consent was requested from each patient at the time of enrollment. The study was performed in accordance with the rules of Good Clinical Practice (GCP). No discrimination was applied in the enrollment of patients in terms of ethnicity, sexual, religious or political orientation. Sensitive data relating to enrolled patients will be kept for 7 years and will be used anonymously according to an alphanumeric coding.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2018
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	Italy: 5
Worldwide total number of subjects	5
EEA total number of subjects	5

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)	0

From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The GLYCEMIA-Heart study has been prematurely interrupted given the very low enrollment rate, and no relevant results could be obtained. The main reasons for such a low recruitment have been identified in the stringent enrollment criteria and, at least in the last 2 years, to the COVID-19 pandemics.

Pre-assignment

Screening details:

The GLYCEMIA-Heart study has been prematurely interrupted given the very low enrollment rate, and no relevant results could be obtained. The main reasons for such a low recruitment have been identified in the stringent enrollment criteria and, at least in the last 2 years, to the COVID-19 pandemics.

Period 1

Period 1 title	treatment (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	treatment

Arm description:

empagliflozin, a sodium-glucose cotransporter inhibitor

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

Dosage and administration details:

1 tablet 10mg once a day

Number of subjects in period 1	treatment
Started	5
Completed	5

Baseline characteristics

Reporting groups	
Reporting group title	treatment

Reporting group description:

The GLYCEMIA-Heart study has been prematurely interrupted given the very low enrollment rate, and no relevant results could be obtained. The main reasons for such a low recruitment have been identified in the stringent enrollment criteria and, at least in the last 2 years, to the COVID-19 pandemics. Moreover, recent international indications have supported the use of SGLT2i in patients with heart failure and reduced ejection fraction, thus limited the possible pool of eligible patients and raising an ethical issue related to the allocation of a subgroup of patients to the "noempagliflozin arm".

Reporting group values	treatment	Total	
Number of subjects	5	5	
Age categorical			
65-80			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	5	5	
85 years and over	0	0	
Age continuous			
65-80			
Units: years			
median	65		
standard deviation	± 5	-	
Gender categorical			
Units: Subjects			
Female	0	0	
Male	5	5	

End points

End points reporting groups

Reporting group title	treatment

Reporting group description:

empagliflozin, a sodium-glucose cotransporter inhibitor

Subject analysis set title	Final report_2018-000832-82
Subject analysis set type	Full analysis

Subject analysis set description:

The GLYCEMIA-Heart study has been prematurely interrupted given the very low enrollment rate, and no relevant results could be obtained. The main reasons for such a low recruitment have been identified in the stringent enrollment criteria and, at least in the last 2 years, to the COVID-19 pandemics. Moreover, recent international indications have supported the use of SGLT2i in patients with heart failure and reduced ejection fraction, thus limited the possible pool of eligible patients and raising an ethical issue related to the allocation of a subgroup of patients to the "noempagliflozin arm".

Primary: Test the effects of empagliflozin on neuro-hormonal activation, as exstimated by 1-year variation in NT-proBNP plasma concentrations.

End point title	Test the effects of empagliflozin on neuro-hormonal activation, as exstimated by 1-year variation in NT-proBNP plasma concentrations.[1]

End point description:

Test the effects of empagliflozin on neuro-hormonal activation, as exstimated by 1-year variation in NT-proBNP plasma concentrations.

End point type	Primary

End point timeframe:

1 year

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: The GLYCEMIA-Heart study has been prematurely interrupted given the very low enrollment rate, and no relevant results could be obtained. The main reasons for such a low recruitment have been identified in the stringent enrollment criteria and, at least in the last 2 years, to the COVID-19 pandemics. Moreover, recent international indications have supported the use of SGLT2i in patients with heart failure and reduced ejection fraction, thus limited the possible pool of eligible patients.

End point values	treatment			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: NT-proBNP plasma concentrations				
number (not applicable)				
NT-proBNP plasma concentrations	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: no SAE during all the study	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	5

Frequency threshold for reporting non-serious adverse events: 0 %

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: no SAE registered

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported