Clinical trial results:
A prospective single-arm, monocentric, phase-II explorative study on evaluation of diagnostic use of the PET tracer (18F)-florbetaben (Neuraceq®) in patient with patient with suspected cardiac amyloidosis

Summary

EudraCT number	2015-005384-16
Trial protocol	IT
Global end of trial date	23 February 2017

Results information

Result version number	v1 (current)
This version publication date	26 May 2022
First version publication date	26 May 2022
Summary attachment (see zip file)	Floramicar Summary (14_Genovesi et al_JACC Cardiov Imaging_2020.pdf)

Trial information

Trial identification

Sponsor protocol code	FLORAMICAR

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 trieste , 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	30 July 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 February 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Establish the affinity of the tracer [18F] -Florbetaben for amyloid deposits in patients with clinican suspition of cardiac amyloidosis AL and ATTR.

Protection of trial subjects:

Study protocol was conformed to the 1975 Declaration of Helsinki. It was approved by the institutional ethics committee and by the Agenzia Italiana del Farmaco committee; all patients provided written informed consent.

Background therapy:

na

Evidence for comparator:

na

Actual start date of recruitment	23 June 2016
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: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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)	10
From 65 to 84 years	2

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Age>20 years, high clinical suspicion of cardiac amyloidosis based on cardiac examination, biomarkers (Nt-proBNP, HS-TnT, immunoglobulin
light chains in serum and urine, plasma protein electrophoresis and serum free light chains), baseline ECG, baseline echocardiography, cardiac MRI, histological evidence of amyloid (Congo red stain).

Pre-assignment

Screening details:

Age>20 years, high clinical suspicion of cardiac amyloidosis based on cardiac examination, biomarkers (Nt-proBNP, HS-TnT, immunoglobulin
light chains in serum and urine, plasma protein electrophoresis and serum free light chains), baseline ECG, baseline echocardiography, cardiac MRI, histological evidence of amyloid (Congo red stain).

Period 1

Period 1 title	[18F]-Florbetaben PET/CT (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

na

Arms

Arm title	Patient with CA

Arm description:

Patient with CA

Arm type	Experimental
Investigational medicinal product name	florbetaben
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Solution for injection

Dosage and administration details:

infusion of 300 MBq/ml of [18F]-Florbetaben followed by a saline flush of 10 ml (1 ml/s)

Number of subjects in period 1	Patient with CA
Started	12
Completed	12

Baseline characteristics

Reporting groups

Reporting group title	[18F]-Florbetaben PET/CT

Reporting group description: -

Reporting group values	[18F]-Florbetaben PET/CT	Total	
Number of subjects	12	12	
Age categorical Units: Subjects			
18-85	12	12	
Gender categorical Units: Subjects			
Female	0	0	
Male	12	12	

Subject analysis sets

Subject analysis set title	18-85
Subject analysis set type	Full analysis

Subject analysis set description:

Patients with ATTR, compared with those with AL and non-CA, were older and presented with higher left atrial volume and
left ventricular mass index (23.5 4.5 ml/m2; p ¼ 0.003 vs. non-CA; and 129 39 g/m2; p ¼ 0.003 vs. non-CA, respectively). Furthermore, whereas patients with CA presented with worse diastolic dysfunction, no difference could be observed in terms of left ventricular systolic function when patients with CA were compared with patients with non-CA.
CARDIAC PET/CT CHARACTERISTICS. Static images qualitative analysis. A total of 240 static cardiac scans (4 scans per patient: early; intermediate; late; and delayed) were evaluated by 2 independent observers. Images indicated a significant radiotracer myocardial uptake in 121 of 240 scans (50%).

Reporting group values	18-85		
Number of subjects	12		
Age categorical Units: Subjects			
18-85	12		
Gender categorical Units: Subjects			
Female			
Male	12		

End points

End points reporting groups

Reporting group title	Patient with CA
Reporting group description: Patient with CA	
Subject analysis set title	18-85
Subject analysis set type	Full analysis
Subject analysis set description: Patients with ATTR, compared with those with AL and non-CA, were older and presented with higher left atrial volume and left ventricular mass index (23.5 4.5 ml/m2; p ¼ 0.003 vs. non-CA; and 129 39 g/m2; p ¼ 0.003 vs. non-CA, respectively). Furthermore, whereas patients with CA presented with worse diastolic dysfunction, no difference could be observed in terms of left ventricular systolic function when patients with CA were compared with patients with non-CA. CARDIAC PET/CT CHARACTERISTICS. Static images qualitative analysis. A total of 240 static cardiac scans (4 scans per patient: early; intermediate; late; and delayed) were evaluated by 2 independent observers. Images indicated a significant radiotracer myocardial uptake in 121 of 240 scans (50%).	

Primary: CA

End point title	CA
End point description:	
End point type	Primary
End point timeframe: only one acquisition	

End point values	Patient with CA	18-85		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	12	12		
Units: SUV mean values	12	12		

Attachments (see zip file)	results/14_Genovesi et al_JACC Cardiov Imaging_2020.pdf

Statistical analyses

Statistical analysis title	results
Comparison groups	Patient with CA v 18-85
Number of subjects included in analysis	24
Analysis specification	Post-hoc
Analysis type	other
P-value	< 0.001
Method	Chi-squared

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

all study

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	all patients

Reporting group description: -

Serious adverse events	all patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	all patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)		

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 OR AE REGISTERED DURING THE STUDY

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