Clinical trial results:
Non-invasive parameters in the evaluation of portal hypertension in patients with liver cirrhosis and their significance for the evolution of cardial complications.

Summary

EudraCT number	2011-001132-30
Trial protocol	CZ
Global end of trial date	31 December 2015

Results information

Result version number	v1 (current)
This version publication date	05 May 2021
First version publication date	05 May 2021
Summary attachment (see zip file)	Article in SJG (eiNOS SJG 2013.pdf)

Trial information

Trial identification

Sponsor protocol code	DIL-2011/04

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	General University Hospital in Prague / Všeobecná fakultní nemocnice v Praze
Sponsor organisation address	U Nemocnice 2, Prague, Czechia, 12808
Public contact	IV. interní klinika, Všeobecná fakultní nemocnice v Praze, 00420 224962580, bruha@cesnet.cz
Scientific contact	IV. interní klinika, Všeobecná fakultní nemocnice v Praze, 00420 224962580, bruha@cesnet.cz

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	31 December 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 December 2015
Global end of trial reached?	Yes
Global end of trial date	31 December 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the relationship between the polymorphisms of beta-2 adrenergic receptors to the treatment response in patients with portal hypertension treated with carvedilol

Protection of trial subjects:

Project was approved by Ethical committee of General University Hospital in Prague.

Background therapy:

It was an observational study on patients treated by carvedilol as a standard of care.

Evidence for comparator:

No comparator.

Actual start date of recruitment	01 September 2011
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	Czechia: 66
Worldwide total number of subjects	66
EEA total number of subjects	66

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)	60
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Observational study - consecutive patients indicated for prophylactic treatment wit betablockers. Only patients in one centre in the Czech Republic.

Pre-assignment

Screening details:

Observational study - consecutive patients indicated for prophylactic treatment wit betablockers. Pre assigment as a part of routine clinical workup.

Period 1

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

Blinding implementation details:

Observational study, no blinding was performed

Arms

Arm title	All patients

Arm description:

It was an observational study.

Arm type	All patients on SOC treatment
Investigational medicinal product name	Carvedilol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

12,5 mg twice a day

Number of subjects in period 1	All patients
Started	66
Completed	66

Baseline characteristics

Reporting groups

Reporting group title	overall trial

Reporting group description:

It was an observational study. The study poppulation was patients with standard of care and laboratory parameters were studied

Reporting group values	overall trial	Total	
Number of subjects	66	66	
Age categorical Units: Subjects			

Age continuous			
Consecutive patients indicated for the preventive treatment with betablockers (standard of care - observational study).			
Units: years			
arithmetic mean	57.2		
standard deviation	± 8.9	-	
Gender categorical Units: Subjects			
Female	22	22	
Male	44	44	

Subject analysis sets

Subject analysis set title	Non-responders
Subject analysis set type	Full analysis

Subject analysis set description:

Patients not responding to SOC

Subject analysis set title	Responders
Subject analysis set type	Full analysis

Subject analysis set description:

Patients responding to SOC

Reporting group values	Non-responders	Responders	
Number of subjects	35	31	
Age categorical Units: Subjects			

Age continuous			
Consecutive patients indicated for the preventive treatment with betablockers (standard of care - observational study).			
Units: years			
arithmetic mean	54.6	59.4	
standard deviation	± 8.4	± 9.9	
Gender categorical Units: Subjects			
Female			

Male			

End points

End points reporting groups

Reporting group title	All patients
Reporting group description: It was an observational study.	
Subject analysis set title	Non-responders
Subject analysis set type	Full analysis
Subject analysis set description: Patients not responding to SOC	
Subject analysis set title	Responders
Subject analysis set type	Full analysis
Subject analysis set description: Patients responding to SOC	

Primary: Response to carvedilol treatment (SOC)

End point title	Response to carvedilol treatment (SOC)
End point description:	
End point type	Primary
End point timeframe: The response to the SCO treatment measured as a decrease of HVPG (in mm Hg) after 1 month therapy.	

End point values	Non-responders	Responders		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	35	31		
Units: mm Hg				
number (not applicable)	35	31		

Statistical analyses

Statistical analysis title	Treatment response
Statistical analysis description: the relationship between the allele frequency and treatment response	
Comparison groups	Responders v Non-responders
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	≤ 0.05
Method	Chi-squared

Adverse events

Adverse events information

Timeframe for reporting adverse events:

This was an obseravational stady on patients indicated for the SOC treatment - measurement and collecting the advserse events were performed 1 month after treatment initialisation.

Assessment type	Non-systematic

Dictionary used

Dictionary name	SUKL (CZ)
Dictionary version	2011

Reporting groups

Reporting group title	All patients

Reporting group description:

All patients indicated for SOC treatment .

Serious adverse events	All patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 66 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	All patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 66 (9.09%)		
Cardiac disorders			
Bradycardia	Additional description: Symptomatic bradycardia		
subjects affected / exposed	6 / 66 (9.09%)		
occurrences (all)	6		

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/23452051