Clinical trial results:
Hyperbaric oxygen treatment in humans with Gram Positive Cocci endocarditis

Summary

EudraCT number	2019-000857-29
Trial protocol	DK
Global end of trial date	30 June 2022

Results information

Result version number	v1 (current)
This version publication date	15 October 2023
First version publication date	15 October 2023

Trial information

Trial identification

Sponsor protocol code	ENDOHOT

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04691440
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Rigshospitalet
Sponsor organisation address	Inge Lehmanns Vej 6, section 6011, Copenhagen N, Denmark, 2100
Public contact	Hyperbaric Unit sect.4092, Rigshospitalet - University Hospital of Copenhagen, ole.hyldegaard@regionh.dk
Scientific contact	Hyperbaric Unit sect.4092, Rigshospitalet - University Hospital of Copenhagen, 45 35454092, ole.hyldegaard@regionh.dk

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	25 October 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 June 2022
Global end of trial reached?	Yes
Global end of trial date	30 June 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess feasibility including patient compliance of adding HyperBaric Oxygen Treatment (HBOT) to the standard management of patients with proven bacterial endocarditis.

Protection of trial subjects:

Feasability study, phaze II. Ethical approval, GCP monitoring and reporting to the Danish Medicines Agency.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2019
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	Denmark: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

26 patients screened for inclusion diagnosed with endocarditis - gram positive cocci endocarditis. Of these 13 patients were excluded. 13 patients where enrolled into the HBOT protocol.

Pre-assignment

Screening details:

13 patients out of 26 screened excluded.

Period 1

Period 1 title	2019-2022 (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	HBOT

Arm description:

Adjuvant HBOT for endocarditis

Arm type	Experimental
Investigational medicinal product name	Conoxia
Investigational medicinal product code	23390
Other name	oxygen
Pharmaceutical forms	Pressurised inhalation
Routes of administration	Respiratory use

Dosage and administration details:

Hyperbaric oxygen. Delivered as inspiratory oxygen fraction of 1.0 at 245 kPa (- or 2.4 ATA, atmospheres absolute pressure) for 90 minutes.

Number of subjects in period 1	HBOT
Started	10
Completed	10

Baseline characteristics

Reporting groups

Reporting group title	2019-2022

Reporting group description: -

Reporting group values	2019-2022	Total	
Number of subjects	10	10	
Age categorical			
Patients with confirmed gram possitive endocarditis and > 18 years of age			
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	10	10	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	80		
full range (min-max)	73.2 to 82.8	-	
Gender categorical			
Units: Subjects			
Female	3	3	
Male	7	7	

Subject analysis sets

Subject analysis set title	Patient compliance
Subject analysis set type	Full analysis

Subject analysis set description:
Patient compliance

Reporting group values	Patient compliance		
Number of subjects	10		
Age categorical			
Patients with confirmed gram possitive endocarditis and > 18 years of age			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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 65-84 years	10		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean	80		
full range (min-max)	73.2 to 82.8		
Gender categorical			
Units: Subjects			
Female	3		
Male	7		

End points

End points reporting groups

Reporting group title	HBOT
Reporting group description:	
Adjuvant HBOT for endocarditis	
Subject analysis set title	Patient compliance
Subject analysis set type	Full analysis
Subject analysis set description:	
Patient compliance	

Primary: Patient compliance

End point title	Patient compliance[1]
End point description:	
End point type	Primary
End point timeframe:	
2019-2022	

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: This is a feasibility study (phase II trial) where testing the practical adjuvant use of HBOT in patients with endocarditis is the primary focus. Sub-group analysis will provide statistiacal comparisons on patients paraclinical data before and after the intervention.

End point values	HBOT	Patient compliance		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	10	10		
Units: number of treatments				
number (not applicable)	10	10		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Non-serious AEs will be collected in the present study only during the HBOT-period. serious AEs is collected, registered in the CRFs and an assessment of causality performed.

Assessment type	Non-systematic

Dictionary used

Dictionary name	GCP monitor
Dictionary version	1

Reporting groups

Reporting group title	ENDOHOT trial

Reporting group description: -

Serious adverse events	ENDOHOT trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (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	ENDOHOT trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 10 (20.00%)		
Psychiatric disorders			
Claustrophobia			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	13		

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