Clinical trial results:
The effect of hyperoxia and hypoxia on fluorescence lifetime imaging ophthalmoscopy in healthy subjects

Summary

EudraCT number	2019-000804-14
Trial protocol	AT
Global end of trial date	02 July 2024

Results information

Result version number	v1 (current)
This version publication date	15 April 2026
First version publication date	15 April 2026

Trial information

Trial identification

Sponsor protocol code	OPHT-070119

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Spitalgasse 23, Vienna, Austria, 1090
Public contact	Department of Clinical Pharmacology, Medical University of Vienna, +43 14040029810, klin-pharmakologie@meduniwien.ac.at
Scientific contact	Department of Clinical Pharmacology, Medical University of Vienna, +43 14040029810, klin-pharmakologie@meduniwien.ac.at

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	02 July 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 July 2024
Global end of trial reached?	Yes
Global end of trial date	02 July 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the effect of 100% oxygen breathing on fluorescence lifetime imaging ophthalmoscopy (FLIO) in healthy subjects

Protection of trial subjects:

not applicable- healthy volunteers

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 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	Austria: 48
Worldwide total number of subjects	48
EEA total number of subjects	48

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)	48
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from the database of the Department of Clinical Pharmacology

Pre-assignment

Screening details:

A screening examination was carried out on each study participant, which included medical history, urine pregnancy test in women with childbearing potential, physical examination, 12-lead electrocardiogram, hemodynamic measurements and a complete ophthalmological examination.

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	Subject, Investigator

Blinding implementation details:

Neither the subject nor the investigator where aware which gas mixture the subject was about to receive.

Arms

Are arms mutually exclusive?	No
Arm title	Hyperoxia

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Oxygen 100%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation vapour
Routes of administration	Inhalation use

Dosage and administration details:

SAUERSTOFF medizinisch, Messer GmbH, Industriestrasse 5, 2352 Gumpoldskirchen, Austria. Dose: 100%, breathing for a maximum of 30min.

Arm title	Hypoxia

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Nitrogen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation vapour
Routes of administration	Inhalation use

Dosage and administration details:

STICKSTOFF medizinisch, Messer GmbH, Industriestrasse 5, 2352 Gumpoldskirchen, Austria. Dose: 88% nitrogen in 12% oxygen, breathing for a maximum of 30min.

Number of subjects in period 1	Hyperoxia	Hypoxia
Started	47	48
Completed	47	47
Not completed	0	1
Adverse event, non-fatal	-	1

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	48	48	
Age categorical 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)	48	48	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	24	24	
Male	24	24	

End points

End points reporting groups	
Reporting group title	Hyperoxia
Reporting group description: -	
Reporting group title	Hypoxia
Reporting group description: -	

Primary: Change in retinal oxygen extraction from baseline	
End point title	Change in retinal oxygen extraction from baseline
End point description:	
End point type	Primary
End point timeframe:	
Before and during gas breathing.	

End point values	Hyperoxia	Hypoxia		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	22		
Units: percent				
arithmetic mean (standard deviation)	-36 (± 17)	6 (± 13)		

Statistical analyses

Statistical analysis title	Difference between groups
Comparison groups	Hyperoxia v Hypoxia
Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	ANOVA

Adverse events

Adverse events information	
Timeframe for reporting adverse events: During the whole study period.	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	26
Reporting groups	
Reporting group title	Study participants

Reporting group description: -

Serious adverse events	Study participants		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 48 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Study participants		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 48 (14.58%)		
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 48 (4.17%)		
occurrences (all)	2		
Dizziness			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences (all)	1		
General disorders and administration site conditions			
Presyncope			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences (all)	1		
Eye disorders			

Eyelid swelling subjects affected / exposed occurrences (all)	1 / 48 (2.08%) 1		
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	1 / 48 (2.08%) 1		
Infections and infestations Covid-19 infection subjects affected / exposed occurrences (all)	1 / 48 (2.08%) 1		

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