Clinical trial results:
Effects of Hyperoxia on Haemostasis, Inflammation and oxidative Stress

Summary

EudraCT number	2015-003962-10
Trial protocol	AT
Global end of trial date	31 December 2019

Results information

Result version number	v1 (current)
This version publication date	12 July 2020
First version publication date	12 July 2020

Trial information

Trial identification

Sponsor protocol code	DOA_HO

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 Anaesthesia, Medical University of Vienna, 0043 14040041440, gisela.scharbert@meduniwien.ac.at
Scientific contact	Department of Anaesthesia, Medical University of Vienna, 0043 14040041440, gisela.scharbert@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	13 December 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 December 2018
Global end of trial reached?	Yes
Global end of trial date	31 December 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Hyperoxia induces ROS in leucocytes

Protection of trial subjects:

Stress monitoring (ECG, bloodpressure) during inhalation

Background therapy:

none

Evidence for comparator: -

Actual start date of recruitment	01 April 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	Austria: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	30
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

For recruitment information sheets were placed at the Medical University of Vienna

Pre-assignment

Screening details:

Peripheral venipuncture was performed to determine blood count and confirm the absences of liver diseases, kidney diseases, and coagulation disorders.

Period 1

Period 1 title	Inhalation (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Data analyst

Arms

Are arms mutually exclusive?	Yes
Arm title	Intervention A

Arm description:

Inhalation 100% Oxygen for 20 minutes
3 weeks wash out period
Inhalation 21% Oxygen for 20 minutes

Arm type	Cross-Over Intervention A
Investigational medicinal product name	Oxygen MedicAL 100% (V/V)
Investigational medicinal product code	6948638.00.00
Other name	
Pharmaceutical forms	Medicinal gas, compressed
Routes of administration	Inhalation use

Dosage and administration details:

20 minutes inhalation of 100% medical oxygen

Investigational medicinal product name	Air synthetical medical AIR LIQUIDE
Investigational medicinal product code	PL1
Other name	
Pharmaceutical forms	Medicinal gas, compressed
Routes of administration	Inhalation use

Dosage and administration details:

20 minutes inhalation of Air synthetical medical gas: Oxygen 21-22,5% O2 Nitrogen 77,5-79,0% N2

Arm title	Intervention B

Arm description:

Inhalation 21% Oxygen for 20 minutes
3 weeks wash out period
Inhalation 100% Oxygen for 20 minutes

Arm type	Cross-Over Intervention B
Investigational medicinal product name	Oxygen MedicAL 100% (V/V)
Investigational medicinal product code	6948638.00.00
Other name	
Pharmaceutical forms	Medicinal gas, compressed
Routes of administration	Inhalation use

Dosage and administration details:

20 minutes inhalation of 100% medical oxygen

Investigational medicinal product name	Air synthetical medical AIR LIQUIDE
Investigational medicinal product code	PL1
Other name	
Pharmaceutical forms	Medicinal gas, compressed
Routes of administration	Inhalation use

Dosage and administration details:

20 minutes inhalation of Air synthetical medical gas: Oxygen 21-22,5% O2 Nitrogen 77,5-79,0% N2

Number of subjects in period 1	Intervention A	Intervention B
Started	15	15
Completed	15	15

Baseline characteristics

Reporting groups	
Reporting group title	Inhalation

Reporting group description: -

Reporting group values	Inhalation	Total	
Number of subjects	30	30	
Age categorical Units: Subjects			
Adults (18-64 years)	30	30	
Gender categorical Units: Subjects			
Male	30	30	

End points

End points reporting groups

Reporting group title	Intervention A
Reporting group description:	
Inhalation 100% Oxygen for 20 minutes 3 weeks wash out period Inhalation 21% Oxygen for 20 minutes	
Reporting group title	Intervention B
Reporting group description:	
Inhalation 21% Oxygen for 20 minutes 3 weeks wash out period Inhalation 100% Oxygen for 20 minutes	

Primary: ROS in leukocytes

End point title	ROS in leukocytes
End point description:	
End point type	Primary
End point timeframe:	
3h	

End point values	Intervention A	Intervention B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: Mean Fluorescence Intensity				
arithmetic mean (standard deviation)	10999 (± 8765)	6371 (± 2114)		

Statistical analyses

Statistical analysis title	Primary Endpoint
Comparison groups	Intervention A v Intervention B
Number of subjects included in analysis	30
Analysis specification	Post-hoc
Analysis type	other[1]
P-value	≤ 0.025
Method	ANOVA

Notes:

[1] - cross-over ANOVA model with random patient factor and adjusting for period and baseline value

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: Continuously during study	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	23

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 non-serious adverse events are recorded

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