Clinical trial results:
The effect of Tetrahydrocannabinol on ocular hemodynamics in healthy subjects

Summary

EudraCT number	2017-004852-52
Trial protocol	AT
Global end of trial date	27 November 2018

Results information

Result version number	v1 (current)
This version publication date	26 January 2020
First version publication date	26 January 2020

Trial information

Trial identification

Sponsor protocol code	OPHT-141117

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	Währinger Gürtel 18-20, Vienna , Austria,
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	27 December 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 November 2018
Global end of trial reached?	Yes
Global end of trial date	27 November 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the effect of single administration of Tetrahydrocannabinol (THC) on ocular blood flow and its regulation.

Protection of trial subjects:

Subjects were during the trial continuously under the supervision of an physician or an experienced nurse.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 May 2018
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: 25
Worldwide total number of subjects	25
EEA total number of subjects	25

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)	25
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited using the data base of the clinical pharmacology, medical university of Vienna.

Pre-assignment

Screening details:

Check of the in- and exclusion criteria, physical examination, vital signs, laboratory assessment

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

Arms

Are arms mutually exclusive?	No
Arm title	Medication

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Dronabinol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

5mg once

Arm title	Placebo

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

1 capsule identical in appearance to Dronabinol capsules without an active ingredient. Placebo will also be taken together 15g butter, 2 pieces of bread and 250ml of water.

Number of subjects in period 1	Medication	Placebo
Started	25	25
Completed	24	24
Not completed	1	1
Lost to follow-up	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	25	25	
Age categorical			
Men and women aged between 18 and 35 years			
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)	25	25	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	13	13	
Male	12	12	

End points

End points reporting groups	
Reporting group title	Medication
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: The effect of single administration of Tetrahydrocannabinol (THC) on ocular blood flow and	
End point title	The effect of single administration of Tetrahydrocannabinol (THC) on ocular blood flow and
End point description:	
End point type	Primary
End point timeframe: one hour after drug administration	

End point values	Medication	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	24		
Units: arbitrary units	24	24		

Statistical analyses

Statistical analysis title	Statistics to end point
Comparison groups	Medication v Placebo
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	ANOVA
Parameter estimate	Cox proportional hazard

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 02.07.2018-27.11.2018	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.1
Reporting groups	
Reporting group title	Adverse events overall trial

Reporting group description: -

Serious adverse events	Adverse events overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 25 (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	Adverse events overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 25 (4.00%)		
Immune system disorders			
Urticaria			
subjects affected / exposed	1 / 25 (4.00%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 July 2018	Changed surname study nurse (wedding)

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported