Clinical trial results:
The effect of Tetrahydrocannabinol on ocular hemodynamics in patients with primary open angle glaucoma- A Phase II Study

Summary

EudraCT number	2019-003089-42
Trial protocol	AT
Global end of trial date	06 August 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-250719

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 4040029810, klin-pharmakologie@meduniwien.ac.at
Scientific contact	Department of Clinical Pharmacology, Medical University of Vienna, +43 4040029810, 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	06 August 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 August 2024
Global end of trial reached?	Yes
Global end of trial date	06 August 2024
Was the trial ended prematurely?	Yes

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 in patients with primary open angle glaucoma and healthy subjects.

Protection of trial subjects:

No specific measures

Background therapy:

Patients with glaucoma continued to take their prescribed intraocular pressure lowering medication during the study.

Evidence for comparator: -

Actual start date of recruitment	25 July 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: 51
Worldwide total number of subjects	51
EEA total number of subjects	51

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)	14
From 65 to 84 years	37
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment was done via the database of the Department of Clinical Pharmacology and co-operating private practices and hospitals.

Pre-assignment

Screening details:

The following examinations and tests were carried out in each patient and healthy subject in the 4 weeks up to 1 day before the first study day:
Informed consent, medical history, urine and blood analysis, physical examination, psychiatric examination, complete opthalmic 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, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	5mg Dronabinol

Arm description:

Patients were randomized to receive 5mg Dronabinol on one study day and Placebo on the other study day.

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

Dosage and administration details:

- Experimental Day: 1 capsule containing 5 mg Dronabinol and 1 capsule Placebo taken together with 15g butter, 2 pieces of bread and 250ml of water
- Placebo Day: 2 capsules Placebo taken together with 15g butter, 2 pieces of bread and 250ml of water

Arm title	10mg Dronabinol

Arm description:

Patients were randomized to receive 10mg Dronabinol on one study day and Placebo on the other study day.

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

Dosage and administration details:

Experimental Day: 2 capsules containing 5 mg Dronabinol (total dose 10 mg) taken together with 15g butter, 2 pieces of bread and 250ml of water
Placebo Day: 2 capsules Placebo taken together with 15g butter, 2 pieces of bread and 250ml of water

Number of subjects in period 1	5mg Dronabinol	10mg Dronabinol
Started	24	27
Completed	23	23
Not completed	1	4
Consent withdrawn by subject	1	4

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	51	51	
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)	14	14	
From 65-84 years	37	37	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	31	31	
Male	20	20	

End points

End points reporting groups

Reporting group title	5mg Dronabinol
Reporting group description:	
Patients were randomized to receive 5mg Dronabinol on one study day and Placebo on the other study day.	
Reporting group title	10mg Dronabinol
Reporting group description:	
Patients were randomized to receive 10mg Dronabinol on one study day and Placebo on the other study day.	

Primary: Relative change in optic nerve head blood flow (MA) in glaucoma patients

End point title	Relative change in optic nerve head blood flow (MA) in glaucoma patients
End point description:	
End point type	Primary
End point timeframe:	
change from baseline after drug administration	

End point values	5mg Dronabinol	10mg Dronabinol		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	12		
Units: percent				
arithmetic mean (standard deviation)	-2.2 (± 7.9)	10.8 (± 20.6)		

Statistical analyses

Statistical analysis title	Difference between groups
Comparison groups	5mg Dronabinol v 10mg Dronabinol
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	ANOVA

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
First Subject first visit - last Subject last visit	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	26

Reporting groups	
Reporting group title	5mg Dronabinol
Reporting group description:	
Patients were randomized to receive 5mg Dronabinol on one study day and Placebo on the other study day.	
Reporting group title	10mg Dronabinol
Reporting group description:	
Patients were randomized to receive 10mg Dronabinol on one study day and Placebo on the other study day.	

Serious adverse events	5mg Dronabinol	10mg Dronabinol	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	5mg Dronabinol	10mg Dronabinol	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 24 (50.00%)	24 / 27 (88.89%)	
Nervous system disorders			
Dizziness			
subjects affected / exposed	4 / 24 (16.67%)	8 / 27 (29.63%)	
occurrences (all)	4	8	
Lightheadedness			
subjects affected / exposed	2 / 24 (8.33%)	4 / 27 (14.81%)	
occurrences (all)	2	4	
Headache			

subjects affected / exposed	1 / 24 (4.17%)	2 / 27 (7.41%)	
occurrences (all)	1	2	
Altered perception			
subjects affected / exposed	1 / 24 (4.17%)	2 / 27 (7.41%)	
occurrences (all)	1	2	
General disorders and administration site conditions			
Tiredness			
subjects affected / exposed	1 / 24 (4.17%)	2 / 27 (7.41%)	
occurrences (all)	1	2	
Syncope			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	
occurrences (all)	0	1	
Feeling of weakness			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 24 (4.17%)	2 / 27 (7.41%)	
occurrences (all)	1	2	
Vomiting			
subjects affected / exposed	1 / 24 (4.17%)	2 / 27 (7.41%)	
occurrences (all)	1	2	
Renal and urinary disorders			
Increased urge to urinate			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	
occurrences (all)	1	0	

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/40772417