Clinical trial results:
Detection of acetylsalicylic acid and omega-3 fatty acids in Schirmers' test strips using mass spectrometry and correlations with tear film and blood flow parameters in healthy adults: an open-label pilot study

Summary

EudraCT number	2020-004978-22
Trial protocol	AT
Global end of trial date	30 November 2021

Results information

Result version number	v1 (current)
This version publication date	16 April 2023
First version publication date	16 April 2023

Trial information

Trial identification

Sponsor protocol code	OPHT-300920

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	Waehringer Guertel 18-20, 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	30 November 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 November 2021
Global end of trial reached?	Yes
Global end of trial date	30 November 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To detect acetylsalicylic acid/omega-3 fatty acids concentrations in healthy adults in tear fluid of Schirmer test strips using untargeted mass spectrometry after intake for one week.
- Change of tear fluid composition from baseline to follow-up visit

Protection of trial subjects:

not applicable - healthy volunteers

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 March 2021
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: 32
Worldwide total number of subjects	32
EEA total number of subjects	32

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)	32
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

recruitment was done via the database of the department of clinical pharmacology

Pre-assignment

Screening details:

The following examinations and tests were carried out in each participant in the 14 days before the first study day:
1. Informed consent
2. Medical History (including ocular medical history)
3. Pregnancy test in women with childbearing potential
4. Ophthalmic examination

Period 1

Period 1 title	active phase (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1: Acetylsalicylic acid

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Aspirin® 500 mg Tabletten
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 tablet per day for 1 week, intake in the evening

Arm title	Group 2: Omega-3 fatty acids 870 mg

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Dr. Böhm® Omega 3 complex 870 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2 tablets per day for 1 week, intake in the evening

Number of subjects in period 1	Group 1: Acetylsalicylic acid	Group 2: Omega-3 fatty acids 870 mg
Started	16	16
Completed	16	16

Baseline characteristics

Reporting groups	
Reporting group title	active phase

Reporting group description: -

Reporting group values	active phase	Total	
Number of subjects	32	32	
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)	32	32	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	15	15	
Male	17	17	

End points

End points reporting groups

Reporting group title	Group 1: Acetylsalicylic acid
Reporting group description: -	
Reporting group title	Group 2: Omega-3 fatty acids 870 mg
Reporting group description: -	

Primary: Concentration of omega-3 fatty acids/acetylsalicylic acid detectable in Schirmer’s tear strips

End point title	Concentration of omega-3 fatty acids/acetylsalicylic acid detectable in Schirmer’s tear strips[1]
End point description:	
Samples have not yet been analyzed, analysis will be performed within the next 12 months.	
End point type	Primary
End point timeframe:	
after 1 week intake of study medication	

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: Samples have not yet been analyzed, analysis will be performed within the next 12 months.

End point values	Group 1: Acetylsalicylic acid	Group 2: Omega-3 fatty acids 870 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: ng/µl	0	0		

Statistical analyses

No statistical analyses for this end point

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	Acetylsalicylic acid
Reporting group description: -	
Reporting group title	Omega-3 fatty acids 870 mg
Reporting group description: -	

Serious adverse events	Acetylsalicylic acid	Omega-3 fatty acids 870 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (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: 1 %

Non-serious adverse events	Acetylsalicylic acid	Omega-3 fatty acids 870 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 16 (6.25%)	6 / 16 (37.50%)	
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 16 (0.00%)	2 / 16 (12.50%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Rhinitis			

subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Cough			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Nasopharyngitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Infections and infestations			
Oral herpes			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	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