



Clinical trial results:

LONG-TERM 24-HOUR INTRAOCULAR PRESSURE CONTROL AND PROGRESSION RATE OBTAINED WITH THE ASSOCIATION OF COMBIGAN IN THE MORNING AND GANFORT IN THE EVENING COMPARED WITH LATANOPROST IN HIGH RISK OPEN-ANGLE GLAUCOMA.

Summary

EudraCT number	2013-001634-17
Trial protocol	IT
Global end of trial date	19 December 2016

Results information

Result version number	v1 (current)
This version publication date	15 July 2026
First version publication date	15 July 2026
Summary attachment (see zip file)	Report MAF-ISS-OPH-GLA-035 (Report MAF-ISS-OPH-GLA-035.pdf)

Trial information

Trial identification

Sponsor protocol code	MAF/ISS/OPH/GLA/035
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	AZIENDA OSPEDALIERA SAN PAOLO
Sponsor organisation address	Via Antonio di rudinì 8, Milan, Italy, 20142
Public contact	Director of ophthalmology, AZIENDA OSPEDALIERA SAN PAOLO, 02 50323150, luca.rossetti@unimi.it
Scientific contact	Director of ophthalmology, AZIENDA OSPEDALIERA SAN PAOLO, 02 50323150, luca.rossetti@unimi.it

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	01 February 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 October 2016
Global end of trial reached?	Yes
Global end of trial date	19 December 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare for the first time the quality of 24-hour IOP control obtained after 3 and 24 months of therapy with the combined administration of Combigan in the morning and Ganfort in the evening versus latanoprost administered once in the evening, in high risk newly diagnosed untreated patients with primary open-angle glaucoma (POAG), or exfoliative glaucoma (XFG) with IOP equal to or greater than 27 mm Hg and a visual field defect with an MD of at least -5 dB.

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 April 2013
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	Italy: 30
Country: Number of subjects enrolled	Greece: 30
Worldwide total number of subjects	60
EEA total number of subjects	60

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	30
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

patient screened with the medical chart and recruited during visits in clinic

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm A

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Latanaprost
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops
Routes of administration	Ophthalmic use

Dosage and administration details:

One drop in the evening

Arm title	Arm b
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	Ganfort and combigan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops
Routes of administration	Ophthalmic use

Dosage and administration details:

one drops of combigan in the morning and one drop of ganfort in the evening

Number of subjects in period 1	Arm A	Arm b
Started	30	30
Completed	28	27
Not completed	2	3
Physician decision	2	3

Baseline characteristics

End points

End points reporting groups

Reporting group title	Arm A
Reporting group description: -	
Reporting group title	Arm b
Reporting group description: -	

Primary: 24 hour iop control difference between group

End point title	24 hour iop control difference between group
End point description:	
End point type	Primary
End point timeframe:	
24 hour iop measure at 3, 8, 12,18 and 24 months from starting therapy	

End point values	Arm A	Arm b		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	28	27		
Units: mmhg				
arithmetic mean (standard deviation)	19.2 (± 2.2)	17.2 (± 2.2)		

Statistical analyses

Statistical analysis title	multivariate linear mixed model
Comparison groups	Arm A v Arm b
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	other ^[1]
P-value	≤ 0.05
Method	Mixed models analysis

Notes:

[1] - multivariate linear mixed model that had the Arm, the Visit and the Time of day as predictors and the IOP as the response variable

Adverse events

Adverse events information

Timeframe for reporting adverse events:

30-apr-2013 to 19-Dec-2016

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	16
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Reporting groups

Reporting group title	Arm A
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Reporting group description: -

Reporting group title	Arm b
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Reporting group description: -

Serious adverse events	Arm A	Arm b	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Arm A	Arm b	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 30 (6.67%)	3 / 30 (10.00%)	
Eye disorders			
hyperemia			
subjects affected / exposed	2 / 30 (6.67%)	3 / 30 (10.00%)	
occurrences (all)	1	1	
uncontrolled iop			
subjects affected / exposed	2 / 30 (6.67%)	3 / 30 (10.00%)	
occurrences (all)	1	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