

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)	121
From 65 to 84 years	0
85 years and over	0

Number of subjects in period 1	Avacincaptad Pegol	Sham
Started	61	60
Safety Analysis Set (SAF)	61	58
Completed	44	53
Not completed	17	7
Adverse event, serious fatal	1	-
Adverse event, non-fatal	4	1
Other	2	1
Subject request	7	3
Lost to follow-up	2	-
Protocol deviation	1	2

Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	12	14	26
Not Hispanic or Latino	49	46	95
Unknown or Not Reported	0	0	0
Area of Ellipsoid Zone Defect			
The area of ellipsoid zone defect was measured by en face spectral domain-optical coherence tomography. ITT included all participants who were randomized. Participants were analyzed according to the treatment to which they were assigned at the time of randomization regardless of the actual study drug the participant may have received during the participation in the study. Only participants with available data at Baseline were included.			
Units: mm ²			
arithmetic mean	4.31	3.94	
standard deviation	± 4.85	± 2.46	-

End points

End points reporting groups

Reporting group title	Avacincaptad Pegol
Reporting group description: The participants received ACP 2 mg/eye on Day 1, Month 1, and Month 2 in the following sequence, 14 days apart in the Induction Phase: o D0: ACP 2 mg/eye o D14: ACP 2 mg/eye And the participants then received ACP 4 mg/eye monthly (Month 3 – Month 17) in the Maintenance Phase.	
Reporting group title	Sham
Reporting group description: The participants received Sham on Day 1, Month 1, and Month 2 in the following sequence, 14 days apart in the Induction Phase: o D0: Sham o D14: Sham And the participants then received Sham monthly (Month 3 – Month 17) in the Maintenance Phase.	

Primary: Mean Rate of Change in the Area of Ellipsoid Zone Defect from Baseline through Month 18

End point title	Mean Rate of Change in the Area of Ellipsoid Zone Defect from Baseline through Month 18
End point description: The area of ellipsoid zone defect was measured by en face spectral domain-optical coherence tomography. Rate of change (slope) in the area of ellipsoid zone defect from Baseline through Month 18 was estimated using mixed model for repeated measures (MMRM). ITT included all participants who were randomized. Participants were analyzed according to the treatment to which they were assigned at the time of randomization regardless of the actual study drug the participant may have received during the participation in the study. Participants with either a non-missing baseline or non-missing post-baseline assessment were included.	
End point type	Primary
End point timeframe: Baseline to Month 18	

End point values	Avacincaptad Pegol	Sham		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	61	58		
Units: mm ² /18 months				
least squares mean (standard error)	0.6383 (± 0.1113)	0.6644 (± 0.1081)		

Statistical analyses

Statistical analysis title	ACP versus (vs.) Sham
Comparison groups	Avacincaptad Pegol v Sham

Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5145
Method	Mixed models analysis
Parameter estimate	difference in LS mean
Point estimate	0.758
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.592
upper limit	3.108
Variability estimate	Standard error of the mean
Dispersion value	1.1487

Secondary: Number of Participants with Adverse Events (AEs)

End point title	Number of Participants with Adverse Events (AEs)
End point description:	
<p>An AE is defined as any untoward medical occurrence in a participant including unfavorable and unintended signs, symptoms or disease temporally associated with the use of a medicinal product and which does not necessarily have to have a causal relationship to this treatment.</p> <p>AEs include illnesses with onset during the trial, or exacerbations of pre-existing illnesses. Exacerbation of pre-existing illness is defined as a significant increase in the severity of the illness as compared to the start of the trial and was considered when a participant requires new or additional treatment for that illness. Lack of or insufficient clinical response or efficacy was not recorded as an AE.</p> <p>Safety Analysis Set (SAF) included all participants who received at least one dose of study drug. Participants were analyzed in the ACP group if they ever received ACP at any time during the study. Participants that received Sham and never received ACP were analyzed in the Sham group.</p>	
End point type	Secondary
End point timeframe:	
Up to 18 months	

End point values	Avacincaptad Pegol	Sham		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	61	58		
Units: Participants	53	45		

Statistical analyses

No statistical analyses for this end point

Hypertension subjects affected / exposed occurrences (all)	3 / 58 (5.17%) 3	1 / 61 (1.64%) 1	
Nervous system disorders Headache subjects affected / exposed occurrences (all)	9 / 58 (15.52%) 30	9 / 61 (14.75%) 30	
Eye disorders Dry eye subjects affected / exposed occurrences (all)	5 / 58 (8.62%) 5	4 / 61 (6.56%) 4	
Conjunctival oedema subjects affected / exposed occurrences (all)	0 / 58 (0.00%) 0	5 / 61 (8.20%) 26	
Eye pain subjects affected / exposed occurrences (all)	7 / 58 (12.07%) 10	9 / 61 (14.75%) 24	
Ocular hyperaemia subjects affected / exposed occurrences (all)	1 / 58 (1.72%) 1	4 / 61 (6.56%) 6	
Punctate keratitis subjects affected / exposed occurrences (all)	4 / 58 (6.90%) 6	8 / 61 (13.11%) 13	
Seasonal allergy subjects affected / exposed occurrences (all)	3 / 58 (5.17%) 4	1 / 61 (1.64%) 1	
Vision blurred subjects affected / exposed occurrences (all)	3 / 58 (5.17%) 3	4 / 61 (6.56%) 4	
Vitreous detachment subjects affected / exposed occurrences (all)	1 / 58 (1.72%) 1	4 / 61 (6.56%) 4	
Vitreous floaters subjects affected / exposed occurrences (all)	1 / 58 (1.72%) 1	7 / 61 (11.48%) 9	
Conjunctival haemorrhage			

subjects affected / exposed occurrences (all)	10 / 58 (17.24%) 21	31 / 61 (50.82%) 140	
Conjunctival hyperaemia subjects affected / exposed occurrences (all)	5 / 58 (8.62%) 13	6 / 61 (9.84%) 9	
Eye irritation subjects affected / exposed occurrences (all)	5 / 58 (8.62%) 15	8 / 61 (13.11%) 12	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	0 / 58 (0.00%) 0	5 / 61 (8.20%) 6	
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	3 / 58 (5.17%) 3	1 / 61 (1.64%) 1	
Influenza subjects affected / exposed occurrences (all)	5 / 58 (8.62%) 5	0 / 61 (0.00%) 0	
Nasopharyngitis subjects affected / exposed occurrences (all)	11 / 58 (18.97%) 19	12 / 61 (19.67%) 13	
Sinusitis subjects affected / exposed occurrences (all)	3 / 58 (5.17%) 3	3 / 61 (4.92%) 3	
Urinary tract infection subjects affected / exposed occurrences (all)	4 / 58 (6.90%) 4	6 / 61 (9.84%) 8	

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