



Clinical trial results:

A prospective, observer-masked, randomized clinical trial to investigate and compare the clinical efficacy of chloroprocaine 3% gel and tetracaine 0.5% eye drop as topical anesthetics in phacoemulsification.

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2019-001660-30 |
| Trial protocol | SK ES IT |
| Global end of trial date | 09 March 2021 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 19 May 2022 |
| First version publication date | 19 May 2022 |

Trial information

Trial identification

| | |
|-----------------------|-----------------|
| Sponsor protocol code | CHL.3/01-2019/M |
|-----------------------|-----------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT04685538 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Sintetica SA |
| Sponsor organisation address | Via Penate 5, Mendrisio, Switzerland, 6850 |
| Public contact | Clinical Operations, Iris Pharma, +33 493594959, |
| Scientific contact | Clinical Operations, Iris Pharma, +33 493594959, |

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 | 03 November 2021 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 09 March 2021 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

Equivalence evaluation of Test versus Reference products in terms of proportion of subjects with a successful surface anesthesia for cataract surgery, without any supplementation at T4 (just before Intra Ocular Lens implantation)

Successful surface anesthesia & Supplementation are defined in the study protocol.

Protection of trial subjects:

For ensuring the protection of the subjects, inclusion and exclusion criteria were assessed at visit 1 for and the proper safety assessemtn and adverse event collection throughout the whole study duration.

Background therapy:

not applicable

Evidence for comparator:

Current practices for ocular topical anesthesia in Europe include topical liquid Oxybuprocaine, Tetracaine and Lidocaine. Tetracaine was chosen among them.

| | |
|---|---------------|
| Actual start date of recruitment | 27 April 2020 |
| 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 | Slovakia: 130 |
| Country: Number of subjects enrolled | Spain: 17 |
| Country: Number of subjects enrolled | Italy: 263 |
| Worldwide total number of subjects | 410 |
| EEA total number of subjects | 410 |

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) | 112 |
| From 65 to 84 years | 282 |
| 85 years and over | 16 |

Subject disposition

Recruitment

Recruitment details:

Patients scheduled to undergo cataract surgery in a single eye at a time for a day surgery

Pre-assignment

Screening details:

Visit 1: between Day -90 and Day -1

ICF; Verification of incl/excl criteria, demography data; pregnancy test; Ocular and systemic medical and surgical histories; Previous and ConMeds; Ocular symptoms; Best-far corrected visual acuity; Slit lamp examination; IOP; Endothelial cell count; Fundoscopy; Pachymetry; Macular optical coherence tomography; CV parameters

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 |

Blinding implementation details:

This was a masked-observer study.

The surgeon placing the gel/drop was aware of the treatment administered. He/she was not to be further involved in patient's care, and data recording and all the study variables were to be evaluated and recorded by another investigator

The surgeon was to be only involved in patient surgery and in satisfaction assessment.

An independent masked investigator was to evaluate sensory block and safety parameters for each patient.

The patient was to be masked.

Arms

| | |
|------------------------------|----------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Chloroprocaine |

Arm description:

Chloroprocaine 3% Gel ophthalmic gel

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | Chloroprocaine hydrochloride 3% eye gel |
| Investigational medicinal product code | CAS number: 3858-89-7 |
| Other name | |
| Pharmaceutical forms | Eye gel |
| Routes of administration | Conjunctival use |

Dosage and administration details:

Dose: 1 drop

Frequency: 3 times

Administration route: Topical instillation

| | |
|------------------|------------|
| Arm title | Tetracaine |
|------------------|------------|

Arm description:

Tetracaine 0.5% eye-drop ophthalmic solution

| | |
|--|--|
| Arm type | Active comparator |
| Investigational medicinal product name | Tetracaine 0.5% eye-drop ophthalmic solution |
| Investigational medicinal product code | NDC 69292-0317-15 |
| Other name | |
| Pharmaceutical forms | Eye drops, solution |
| Routes of administration | Conjunctival use |

Dosage and administration details:

Dose: 1 drop

Frequency: 3 times

Administration route: Topical instillation

| Number of subjects in period 1 | Chloroprocaine | Tetracaine |
|---------------------------------------|----------------|------------|
| Started | 205 | 205 |
| Completed | 163 | 169 |
| Not completed | 42 | 36 |
| Adverse event, non-fatal | - | 1 |
| not randomized | - | 32 |
| discontinued before treatment | 32 | - |
| discontinued before treatment | - | 1 |
| Lost to follow-up | - | 2 |
| Protocol deviation | 10 | - |

Baseline characteristics

Reporting groups

| | |
|---|---------------|
| Reporting group title | overall trial |
| Reporting group description: | |
| Number of patients enrolled and randomized to receive either IMP or active comparator | |

| Reporting group values | overall trial | Total | |
|--|---------------|-------|--|
| Number of subjects | 410 | 410 | |
| 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) | 112 | 112 | |
| From 65-84 years | 282 | 282 | |
| 85 years and over | 16 | 16 | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 69.37 | | |
| standard deviation | ± 10.11 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 228 | 228 | |
| Male | 182 | 182 | |

Subject analysis sets

| | |
|--|--------------------|
| Subject analysis set title | Enrolled set |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| All patients enrolled in the study. | |
| Subject analysis set title | FAS |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| All patients enrolled in the study for whom any follow-up efficacy information was available. | |
| Subject analysis set title | Safety set |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: | |
| All patients enrolled in the study, for whom there was evidence that they used study medication and for whom any follow-up information was available | |
| Subject analysis set title | PP set |
| Subject analysis set type | Per protocol |
| Subject analysis set description: | |
| All patients of the FAS who did not show any major protocol violation. | |

| Reporting group values | Enrolled set | FAS | Safety set |
|---|--------------|---------|------------|
| Number of subjects | 410 | 338 | 338 |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 112 | 85 | 85 |
| From 65-84 years | 282 | 239 | 239 |
| 85 years and over | 16 | 13 | 13 |
| Age continuous Units: years | | | |
| arithmetic mean | 69.37 | 69.58 | 69.58 |
| standard deviation | ± 10.11 | ± 10.12 | ± 10.12 |
| Gender categorical Units: Subjects | | | |
| Female | 228 | 180 | 180 |
| Male | 182 | 158 | 158 |

| Reporting group values | PP set | | |
|---|---------|--|--|
| Number of subjects | 332 | | |
| Age categorical Units: Subjects | | | |
| In utero | 0 | | |
| Preterm newborn infants (gestational age < 37 wks) | 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) | 85 | | |
| From 65-84 years | 237 | | |
| 85 years and over | 12 | | |
| Age continuous Units: years | | | |
| arithmetic mean | 69.56 | | |
| standard deviation | ± 10.12 | | |
| Gender categorical Units: Subjects | | | |
| Female | 176 | | |
| Male | 156 | | |

End points

End points reporting groups

| | |
|--|--------------------|
| Reporting group title | Chloroprocaine |
| Reporting group description: | |
| Chloroprocaine 3% Gel ophthalmic gel | |
| Reporting group title | Tetracaine |
| Reporting group description: | |
| Tetracaine 0.5% eye-drop ophthalmic solution | |
| Subject analysis set title | Enrolled set |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| All patients enrolled in the study. | |
| Subject analysis set title | FAS |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| All patients enrolled in the study for whom any follow-up efficacy information was available. | |
| Subject analysis set title | Safety set |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: | |
| All patients enrolled in the study, for whom there was evidence that they used study medication and for whom any follow-up information was available | |
| Subject analysis set title | PP set |
| Subject analysis set type | Per protocol |
| Subject analysis set description: | |
| All patients of the FAS who did not show any major protocol violation. | |

Primary: Successful surface anesthesia_Chloroprocaine vs Tetracaine

| | |
|--|--|
| End point title | Successful surface anesthesia_Chloroprocaine vs Tetracaine |
| End point description: | |
| Equivalence evaluation of Chloroprocaine 3% Gel versus Tetracaine 0.5% eye-drop products in terms of proportion of patients with a successful surface anesthesia for cataract surgery, without any supplementation at T4 (just before Intra Ocular Lens implantation). | |
| End point type | Primary |
| End point timeframe: | |
| at T4 in Visit 2 | |

| End point values | Chloroprocaine | Tetracaine | | |
|-----------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 163 ^[1] | 169 ^[2] | | |
| Units: number of subjects | | | | |
| Anesthesia Success_PP_Yes | 150 | 153 | | |
| Anesthesia Success_PP_No | 13 | 16 | | |
| Anesthesia Success_FAS_Yes | 152 | 153 | | |
| Anesthesia Success_FAS_No | 14 | 19 | | |

Notes:

[1] - 163 for the PP
166 for the FAS
[2] - 169 for the PP
172 for the FAS

| | |
|-----------------------------------|---------------------------------|
| Attachments (see zip file) | surface anesthesia at T4_V2.png |
|-----------------------------------|---------------------------------|

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Proportion of successful surface anesthesia at T4 |
| Comparison groups | Tetracaine v Chloroprocaine |
| Number of subjects included in analysis | 332 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence |
| Parameter estimate | estimated difference in proportions |
| Point estimate | 1.5 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -10 |
| upper limit | 10 |
| Variability estimate | Standard deviation |

Secondary: Successful surface anesthesia at T1, T2, T3 during Visit 2_PP

| | |
|---------------------------------|---|
| End point title | Successful surface anesthesia at T1, T2, T3 during Visit 2_PP |
| End point description: | |
| Time points: | |
| T1 - Just before first incision | |
| T2 - End of capsulorhexis | |
| T3 - End of phacoemulsification | |
| End point type | Secondary |
| End point timeframe: | |
| during Visit 2 | |

| | | | | |
|--------------------------------------|-----------------|-----------------|--|--|
| End point values | Chloroprocaine | Tetracaine | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 163 | 169 | | |
| Units: number of subjects | | | | |
| Successful surface anesthesia_T1_Yes | 155 | 163 | | |
| Successful surface anesthesia_T1_No | 8 | 6 | | |
| Successful surface anesthesia_T2_Yes | 159 | 163 | | |
| Successful surface anesthesia_T2_No | 4 | 6 | | |
| Successful surface anesthesia_T3_Yes | 152 | 151 | | |
| Successful surface anesthesia_T3_No | 11 | 18 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Ocular symptoms analysis - Safety set

| | |
|-----------------|---------------------------------------|
| End point title | Ocular symptoms analysis - Safety set |
|-----------------|---------------------------------------|

End point description:

Ocular symptoms (pain, irritation/burning/stinging, photophobia, foreign body sensation) will be graded by the patients according to the following scale: 0 = absent, 1 = mild, 2 = moderate, 3 = severe.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

during the study (Visit 1-Selection and Visit 4-Final)

| End point values | Chloroprocaine | Tetracaine | | |
|--|-----------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 166 | 172 ^[3] | | |
| Units: grading | | | | |
| arithmetic mean (standard deviation) | | | | |
| Foreign body sensation_V1_study eye | 0.08 (± 0.32) | 0.06 (± 0.33) | | |
| Foreign body sensation_V4_study eye | 0.19 (± 0.43) | 0.17 (± 0.41) | | |
| Irritation/burning/stinging_V1_study eye | 0.11 (± 0.33) | 0.11 (± 0.37) | | |
| Irritation/burning/stinging_V4_study eye | 0.11 (± 0.36) | 0.15 (± 0.39) | | |
| Pain_V1_study eye | 0.01 (± 0.11) | 0.01 (± 0.08) | | |
| Pain_V4_study eye | 0.05 (± 0.24) | 0.05 (± 0.24) | | |
| Photophobia_V1_study eye | 0.13 (± 0.42) | 0.08 (± 0.35) | | |
| Photophobia_V4_study eye | 0.18 (± 0.50) | 0.11 (± 0.36) | | |

Notes:

[3] - 169 for all the assessment at visit 4

Statistical analyses

No statistical analyses for this end point

Secondary: Time to obtain sufficient anesthesia and total time (duration) of anesthesia_PP

| | |
|-----------------|---|
| End point title | Time to obtain sufficient anesthesia and total time (duration) of anesthesia_PP |
|-----------------|---|

End point description:

Note: For patients who achieved anesthesia in a time frame of less than a minute, time to obtain anesthesia is set at 1 min.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:
at visit 2

| End point values | Chloroprocaine | Tetracaine | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 163 | 169 | | |
| Units: minute | | | | |
| arithmetic mean (standard deviation) | | | | |
| Time To Obtain Sufficient Anesthesia | 1.35 (± 0.87) | 1.57 (± 1.85) | | |
| Total Duration Of Anesthesia | 21.57 (± 12.26) | 22.04 (± 12.58) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Intraocular pressure analysis - Safety set

| | |
|--------------------------------------|--|
| End point title | Intraocular pressure analysis - Safety set |
| End point description: | |
| End point type | Secondary |
| End point timeframe: at V1 and V4 | |

| End point values | Chloroprocaine | Tetracaine | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 166 | 172 | | |
| Units: mmHg | | | | |
| arithmetic mean (standard deviation) | | | | |
| IOP_V1_study eye | 15.10 (± 2.70) | 15.02 (± 2.46) | | |
| IOP_V4_study eye | 14.73 (± 2.78) | 14.85 (± 3.06) | | |
| IOP_V1_other eye | 14.90 (± 2.41) | 14.88 (± 2.47) | | |
| IOP_V4_other eye | 14.80 (± 2.50) | 14.95 (± 2.41) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Fundoscopy analysis - Safety set

| | |
|-----------------|----------------------------------|
| End point title | Fundoscopy analysis - Safety set |
|-----------------|----------------------------------|

End point description:

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

at V1 and at V4

| End point values | Chloroprocaine | Tetracaine | | |
|-----------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 166 | 172 | | |
| Units: number of subjects | | | | |
| Macula_V1_study eye_abnormal | 15 | 16 | | |
| Macula_V1_study eye_normal | 149 | 152 | | |
| Macula_V4_study eye_abnormal | 13 | 10 | | |
| Macula_V4_study eye_normal | 152 | 159 | | |
| Optic nerve_V1_study eye_abnormal | 16 | 16 | | |
| Optic nerve_V1_study eye_normal | 149 | 153 | | |
| Optic nerve_V4_study eye_abnormal | 12 | 10 | | |
| Optic nerve_V4_study eye_normal | 153 | 159 | | |
| Retina_V1_study eye_abnormal | 13 | 11 | | |
| Retina_V1_study eye_normal | 152 | 158 | | |
| Retina_V4_study eye_abnormal | 13 | 12 | | |
| Retina_V4_study eye_normal | 152 | 157 | | |
| Macula_V1_other eye_abnormal | 14 | 20 | | |
| Macula_V1_other eye_norma | 151 | 152 | | |
| Macula_V4_other eye_abnorma | 10 | 13 | | |
| Macula_V4_other eye_norma | 156 | 155 | | |
| Optic nerve_V1_other eye_abnormal | 17 | 16 | | |
| Optic nerve_V1_other eye_normal | 149 | 156 | | |
| Optic nerve_V4_other eye_abnormal | 14 | 10 | | |
| Optic nerve_V4_other eye_normal | 152 | 158 | | |
| Retina_V1_other eye_abnormal | 12 | 12 | | |
| Retina_V1_other eye_normal | 156 | 160 | | |
| Retina_V4_other eye_abnormal | 14 | 9 | | |
| Retina_V4_other eye_normal | 152 | 159 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Specular microscopy analysis - Safety set

| | |
|-----------------|---|
| End point title | Specular microscopy analysis - Safety set |
|-----------------|---|

End point description:

Endothelial Cells Count [cell/mm2]

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

at V1 and at V4

| End point values | Chloroprocaine | Tetracaine | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 166 ^[4] | 172 ^[5] | | |
| Units: cells/square millimeter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Endothelial Cells Count_V1_study eye | 2440.76 (± 378.01) | 2511.89 (± 325.32) | | |
| Endothelial Cells Count_V4_study eye | 2049.88 (± 620.43) | 2166.96 (± 517.41) | | |

Notes:

[4] - at V4, 161 subjects

[5] - at V4, 165 subjects

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

from visit 2 to visit 5

Adverse event reporting additional description:

All AEs derived by spontaneous, unsolicited reports of the patients, by observation and by routine open questioning were to be collected and reported.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 23.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|------------------------|
| Reporting group title | Choloroprocaine 3% gel |
|-----------------------|------------------------|

Reporting group description:

safety set

| | |
|-----------------------|--------------------------|
| Reporting group title | Tetracaine 0.5% eye drop |
|-----------------------|--------------------------|

Reporting group description:

safety set

| Serious adverse events | Choloroprocaine 3% gel | Tetracaine 0.5% eye drop | |
|---|------------------------|--------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 166 (0.00%) | 0 / 172 (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: 0 %

| Non-serious adverse events | Choloroprocaine 3% gel | Tetracaine 0.5% eye drop | |
|---|------------------------|--------------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 14 / 166 (8.43%) | 19 / 172 (11.05%) | |
| Investigations | | | |
| Blood pressure increased | | | |
| subjects affected / exposed | 0 / 166 (0.00%) | 3 / 172 (1.74%) | |
| occurrences (all) | 0 | 3 | |
| intraoc | | | |
| subjects affected / exposed | 1 / 166 (0.60%) | 3 / 172 (1.74%) | |
| occurrences (all) | 1 | 6 | |
| Injury, poisoning and procedural | | | |

| | | | |
|--|-----------------|-----------------|--|
| complications | | | |
| Incision site oedema | | | |
| subjects affected / exposed | 1 / 166 (0.60%) | 0 / 172 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 166 (0.00%) | 1 / 172 (0.58%) | |
| occurrences (all) | 0 | 1 | |
| Congenital, familial and genetic disorders | | | |
| Corneal dystrophy | | | |
| subjects affected / exposed | 0 / 166 (0.00%) | 1 / 172 (0.58%) | |
| occurrences (all) | 0 | 1 | |
| Nervous system disorders | | | |
| Trigeminal neuralgia | | | |
| subjects affected / exposed | 0 / 166 (0.00%) | 1 / 172 (0.58%) | |
| occurrences (all) | 0 | 1 | |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 166 (0.60%) | 0 / 172 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Sensation of foreign body | | | |
| subjects affected / exposed | 1 / 166 (0.60%) | 0 / 172 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Eye disorders | | | |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 1 / 166 (0.60%) | 0 / 172 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Conjunctivitis allergic | | | |
| subjects affected / exposed | 0 / 166 (0.00%) | 1 / 172 (0.58%) | |
| occurrences (all) | 0 | 1 | |
| Corneal degeneration | | | |
| subjects affected / exposed | 0 / 166 (0.00%) | 1 / 172 (0.58%) | |
| occurrences (all) | 0 | 1 | |
| Corneal disorder | | | |
| subjects affected / exposed | 0 / 166 (0.00%) | 1 / 172 (0.58%) | |
| occurrences (all) | 0 | 1 | |
| Corneal oedema | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 5 / 166 (3.01%) | 2 / 172 (1.16%) | |
| occurrences (all) | 5 | 2 | |
| Eye discharge | | | |
| subjects affected / exposed | 0 / 166 (0.00%) | 1 / 172 (0.58%) | |
| occurrences (all) | 0 | 1 | |
| Hyperaesthesia eye | | | |
| subjects affected / exposed | 1 / 166 (0.60%) | 0 / 172 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Iridocele | | | |
| subjects affected / exposed | 0 / 166 (0.00%) | 1 / 172 (0.58%) | |
| occurrences (all) | 0 | 1 | |
| Lens dislocation | | | |
| subjects affected / exposed | 0 / 166 (0.00%) | 1 / 172 (0.58%) | |
| occurrences (all) | 0 | 1 | |
| Ocular hypertension | | | |
| subjects affected / exposed | 0 / 166 (0.00%) | 1 / 172 (0.58%) | |
| occurrences (all) | 0 | 1 | |
| Photophobia | | | |
| subjects affected / exposed | 1 / 166 (0.60%) | 1 / 172 (0.58%) | |
| occurrences (all) | 1 | 1 | |
| Punctate keratitis | | | |
| subjects affected / exposed | 1 / 166 (0.60%) | 1 / 172 (0.58%) | |
| occurrences (all) | 1 | 1 | |
| Pupillary deformity | | | |
| subjects affected / exposed | 0 / 166 (0.00%) | 1 / 172 (0.58%) | |
| occurrences (all) | 0 | 1 | |
| Pupillary disorder | | | |
| subjects affected / exposed | 0 / 166 (0.00%) | 1 / 172 (0.58%) | |
| occurrences (all) | 0 | 1 | |
| Retinal pigment epitheliopathy | | | |
| subjects affected / exposed | 1 / 166 (0.60%) | 0 / 172 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |

| | | | |
|--|----------------------|----------------------|--|
| subjects affected / exposed occurrences (all) | 1 / 166 (0.60%) 1 | 0 / 172 (0.00%) 0 | |
| Product issues Device dislocation subjects affected / exposed occurrences (all) | 1 / 166 (0.60%) 1 | 1 / 172 (0.58%) 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