# Clinical trial results:
# A Randomized, Double-Blind, Placebo- Controlled, Parallel-Group, Multi-Center Study to Assess the Efficacy of Once-Daily Fluticasone Propionate Aqueous Nasal Spray 200mcg for 14 Days on Ocular Symptoms Associated with Seasonal Allergic Rhinitis

## Summary

| | |
|---|---|
| EudraCT number | 2015-001727-23 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 16 February 2013 |

**Results information**

| | |
|---|---|
| Result version number | v2 (current) |
| This version publication date | 09 June 2017 |
| First version publication date | 08 August 2015 |
| Version creation reason | • Correction of full data set<br>Eudract is showing that results have issues. checking the errors |
| Summary attachment (see zip file) | RH01619 (RH01619-Clinical-Study-Result-Summary.pdf) |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | RH01619 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01817790 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | GlaxoSmithKline Consumer Healthcare |
| Sponsor organisation address | St. George's Avenue, Weybridge, United Kingdom, KT13 0DE |
| Public contact | Clinical trial disclosure desk, GlaxoSmithKline Consumer Healthcare, 866 435-7343, |
| Scientific contact | Clinical trial disclosure desk, GlaxoSmithKline Consumer Healthcare, 866 435-7343, |

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? | Yes |

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 15 May 2013 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 16 February 2013 |
| Global end of trial reached? | Yes |
| Global end of trial date | 16 February 2013 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

To demonstrate that a 14-day course of FP200QD is superior to placebo in relieving ocular symptoms associated with AR as determined by mean change from baseline in subject-rated reflective total ocular symptom scores (rTOSS)

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the World Medical Association Declaration of Helsinki.

The study procedures did not pose any threat to the lives of the patients.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 12 April 2012 |
| 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 | United States: 626 |
| Worldwide total number of subjects | 626 |
| EEA total number of subjects | 0 |

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) | 75 |
| Adults (18-64 years) | 522 |
| From 65 to 84 years | 29 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

Participants were recruited at 6 clinical sites in the US.

### Pre-assignment

Screening details:

Of the 855 participants screened, 626 were randomized in the study. Of the 229 participants not randomized into the study, 151 did not meet the study criteria; 3 developed AEs; 10 were lost to follow-up; 4 violated protocol; 28 withdrew consent; and the remaining 33 were not randomized for other reasons.

### Period 1

| | |
|---|---|
| Period 1 title | Overall Period (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Assessor |

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Fluticasone Propionate Nasal Spray |

Arm description:

Two sprays of Fluticasone propionate nasal spray (50 mcg/spray) per nostril to be administered in morning (Total dose 200 mcg).

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Fluticasone propionate |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Nasal spray |
| Routes of administration | Nasal use |

Dosage and administration details:

50 mcg/spray (16 mL bottle – 120 metered sprays)

| | |
|---|---|
| **Arm title** | Placebo Nasal Spray |

Arm description:

Two sprays of placebo per nostril to be administered in morning

| | |
|---|---|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Nasal spray |
| Routes of administration | Nasal use |

Dosage and administration details:

50 mcg/spray (16 mL bottle – 120 metered sprays)

| **Number of subjects in period 1** | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray |
|---|---|---|
| Started | 314 | 312 |
| Completed | 310 | 304 |
| Not completed | 4 | 8 |
| Consent withdrawn by subject | 1 | 3 |
| Adverse event, non-fatal | - | 2 |
| Lost to follow-up | - | 1 |
| Could not attend appointment | 1 | 1 |
| Protocol deviation | 2 | 1 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Fluticasone Propionate Nasal Spray |
| Reporting group description: | |
| Two sprays of Fluticasone propionate nasal spray (50 mcg/spray) per nostril to be administered in morning (Total dose 200 mcg). | |
| Reporting group title | Placebo Nasal Spray |
| Reporting group description: | |
| Two sprays of placebo per nostril to be administered in morning | |

| Reporting group values | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | Total |
|---|---|---|---|
| Number of subjects | 314 | 312 | 626 |
| Age categorical<br>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) | | | 0 |
| From 65-84 years | | | 0 |
| 85 years and over | | | 0 |
| Age continuous<br>Units: years | | | |
| arithmetic mean | 40.4 | 40.5 | |
| standard deviation | ± 14.55 | ± 16.36 | - |
| Gender categorical<br>Units: Subjects | | | |
| Female | 212 | 201 | 413 |
| Male | 102 | 111 | 213 |
| Race<br>Units: Subjects | | | |
| American Indian or Alaska Native | 1 | 0 | 1 |
| Asian | 1 | 2 | 3 |
| Black or African American | 36 | 38 | 74 |
| White | 272 | 270 | 542 |
| Native Hawaiian or other Pacific Islander | 1 | 1 | 2 |
| Multiple | 3 | 1 | 4 |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | Fluticasone Propionate Nasal Spray |
| Reporting group description: | |
| Two sprays of Fluticasone propionate nasal spray (50 mcg/spray) per nostril to be administered in morning (Total dose 200 mcg). | |
| Reporting group title | Placebo Nasal Spray |
| Reporting group description: | |
| Two sprays of placebo per nostril to be administered in morning | |

### Primary: Mean Change From Baseline in Reflective Total Ocular Symptom Score (rTOSS)

| | |
|---|---|
| End point title | Mean Change From Baseline in Reflective Total Ocular Symptom Score (rTOSS) |
| End point description: | |
| The Reflective Total Ocular Symptom Score (rTOSS) is the sum of 3 individual participant-assessed symptom scores (eye itching/burning, eye tearing/watering, and eye redness), each evaluated using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. Subjects completed rTOSS in the evening (PM rTOSS; 12 hours post morning nasal spray use) and once in the morning (AM score: prior to nasal spray use). Daily (i.e. during one dosing interval) rTOSS is defined as the average of the PM rTOSS and the AM rTOSS of the next day prior to AM dosing. The mean change from baseline in (daily, AM, PM) TOSS was calculated as the subject's treatment period mean (over 14 days; from Day 0 PM to Day 14 AM) minus the baseline period (placebo run-in) mean. | |
| End point type | Primary |
| End point timeframe: | |
| Baseline to 14 days | |

| End point values | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 314 | 312 | | |
| Units: Score on Scale | | | | |
| arithmetic mean (standard deviation) | -0.91 (± 1.625) | -0.63 (± 1.525) | | |

### Statistical analyses

| | |
|---|---|
| **Statistical analysis title** | Reflective Total Ocular Symptom Score (rTOSS) |
| Comparison groups | Placebo Nasal Spray v Fluticasone Propionate Nasal Spray |

| | |
|---|---|
| Number of subjects included in analysis | 626 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.0024 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.36 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.59 |
| upper limit | -0.13 |

## Secondary: Mean Change From Baseline in AM rTOSS

| | |
|---|---|
| End point title | Mean Change From Baseline in AM rTOSS |

End point description:

rTOSS is the sum of 3 individual participant-assessed symptom scores (eye itching/ burning, eye tearing/watering, and eye redness), each evaluated using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. For AM rToss, subject

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

End point timeframe:

Baseline to 14 days

| End point values | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 314 | 312 | | |
| Units: Score on scale | | | | |
| arithmetic mean (standard deviation) | -0.96 (± 1.627) | -0.68 (± 1.573) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Mean Change From Baseline in PM rTOSS

| | |
|---|---|
| End point title | Mean Change From Baseline in PM rTOSS |

End point description:

rTOSS is the sum of 3 individual participant-assessed symptom scores (eye itching/ burning, eye tearing/watering, and eye redness), each evaluated using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. For PM rTOSS, subjects completed rTOSS in the evening, 12 hours post morning nasal spray use. The mean change from baseline in PM rTOSS was calculated as the subject's treatment period mean (over 14 days) minus the baseline period (placebo run-in) mean.

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

End point timeframe:

Baseline to 14 days

| End point values | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 314 | 312 | | |
| Units: Score on scale | | | | |
| arithmetic mean (standard deviation) | -0.87 (± 1.735) | -0.6 (± 1.577) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Mean Change From Baseline in Individual AM Reflective Ocular Symptom Scores for Eye Itching/Burning

| End point title | Mean Change From Baseline in Individual AM Reflective Ocular Symptom Scores for Eye Itching/Burning |
|---|---|

End point description:

The AM Reflective Ocular Symptom Score was assessed individually for eye itching/burning using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. For evaluation, subjects completed the scoring in the morning, prior to nasal spray use. The mean change from baseline in AM Reflective Ocular Symptom Score (eye itching and burning) was calculated as the subject's treatment period mean (over 14 days) minus the baseline period (placebo run-in) mean

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

End point timeframe:

Baseline to 14 days

| End point values | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 314 | 312 | | |
| Units: Score on scale | | | | |
| arithmetic mean (standard deviation) | -0.35 (± 0.581) | -0.28 (± 0.553) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Mean Change From Baseline in Individual PM Reflective Ocular Symptom Scores for Eye Itching/Burning

| End point title | Mean Change From Baseline in Individual PM Reflective Ocular Symptom Scores for Eye Itching/Burning |
|---|---|

End point description:

The PM Reflective Ocular Symptom Score was assessed individually for eye itching/burning using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. For evaluation, subjects completed the scoring in the evening, 12 hours post morning nasal spray use. The mean change from baseline in PM Reflective Ocular Symptom Score (eye itching and burning) was calculated as the subject's treatment period mean (over 14 days) minus the baseline period (placebo run-in) mean

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

End point timeframe:

Baseline to 14 days

| **End point values** | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 314 | 312 | | |
| Units: Score on scale | | | | |
| arithmetic mean (standard deviation) | -0.33 (± 0.626) | -0.24 (± 0.554) | | |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Mean Change From Baseline in Individual AM Reflective Ocular Symptom Scores for Eye Tearing/Watering**

| End point title | Mean Change From Baseline in Individual AM Reflective Ocular Symptom Scores for Eye Tearing/Watering |
|---|---|

End point description:

The AM Reflective Ocular Symptom Score was assessed individually for eye tearing/watering using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. For evaluation, subjects completed the scoring in the morning, prior to nasal spray use. The mean change from baseline in AM Reflective Ocular Symptom Score (eye tearing/watering) was calculated as the subject's treatment period mean (over 14 days) minus the baseline period (placebo run-in) mean.

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

End point timeframe:

Baseline to 14 days

| **End point values** | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 314 | 312 | | |
| Units: Score on sclae | | | | |
| arithmetic mean (standard deviation) | -0.35 (± 0.596) | -0.24 (± 0.589) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Mean Change From Baseline in Individual PM Reflective Ocular Symptom Scores for Eye Tearing/Watering

| End point title | Mean Change From Baseline in Individual PM Reflective Ocular Symptom Scores for Eye Tearing/Watering |
|---|---|

End point description:

The PM Reflective Ocular Symptom Score was assessed individually for eye tearing/watering using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. For evaluation, subjects completed the scoring in the evening, 12 hours post morning nasal spray use. The mean change from baseline in PM Reflective Ocular Symptom Score (eye tearing/watering) was calculated as the subject's treatment period mean (over 14 days) minus the baseline period (placebo run-in) mean.

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

End point timeframe:

Baseline to 14 days

| End point values | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 314 | 312 | | |
| Units: Score on scale | | | | |
| arithmetic mean (standard deviation) | -0.32 (± 0.653) | -0.19 (± 0.586) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Mean Change From Baseline in Individual AM Reflective Ocular Symptom Scores for Eye Redness

| End point title | Mean Change From Baseline in Individual AM Reflective Ocular Symptom Scores for Eye Redness |
|---|---|

End point description:

The AM Reflective Ocular Symptom Score was assessed individually for eye redness using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. For evaluation, subjects completed the scoring in the morning, prior to nasal spray use. The mean change from baseline in AM Reflective Ocular Symptom Score (eye redness) was calculated as the subject's treatment period mean (over 14 days) minus the baseline period (placebo run-in) mean

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

End point timeframe:

Baseline to 14 days

| End point values | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 314 | 312 | | |
| Units: Score on scale | | | | |
| arithmetic mean (standard deviation) | -0.26 (± 0.597) | -0.17 (± 0.613) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Mean Change From Baseline in Individual PM Reflective Ocular Symptom Scores for Eye Redness

| End point title | Mean Change From Baseline in Individual PM Reflective Ocular Symptom Scores for Eye Redness |
|---|---|

End point description:

The PM Reflective Ocular Symptom Score was assessed individually for eye redness using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. For evaluation, subjects completed the scoring in the evening, 12 hours post morning nasal spray use. The mean change from baseline in PM Reflective Ocular Symptom Score (eye redness) was calculated as the subject's treatment period mean (over 14 days) minus the baseline period (placebo run-in) mean.

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

End point timeframe:

Baseline to 14 days

| End point values | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 314 | 312 | | |
| Units: Score on scale | | | | |
| arithmetic mean (standard deviation) | -0.22 (± 0.628) | -0.17 (± 0.635) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Mean Change From Baseline in AM Pre-dose Instantaneous Total Ocular Symptom Scores (iTOSS)

| End point title | Mean Change From Baseline in AM Pre-dose Instantaneous Total Ocular Symptom Scores (iTOSS) |
|---|---|

End point description:

Instantaneous total ocular symptom scores (iTOSS) assessments are self perceived evaluation of symptom severity immediately before the dose (how the subject feels at that point in time). iTOSS (possible score of 0-9) is the sum of 3 individual participant-assessed symptom scores for eye itching/burning, eye tearing/watering, and eye redness each evaluated using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe. Mean changes from baseline were calculated as treatment period iTOSS minus baseline iTOSS.

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

End point timeframe:

Baseline to 14 days

| **End point values** | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 314 | 312 | | |
| Units: Score on a scale | | | | |
| arithmetic mean (standard deviation) | -0.8 (± 1.443) | -0.55 (± 1.531) | | |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Mean Change From Baseline in Reflective Nasal Congestion Symptom Score (rNCSS)**

| End point title | Mean Change From Baseline in Reflective Nasal Congestion Symptom Score (rNCSS) |
|---|---|

End point description:

The rNCSS is a participant perceived evaluation of overall congestion symptom severity (evaluated using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe) which was completed once in the evening (PM), and once in the morning (AM). rNCSS is defined as the average of the PM rNCSS and the AM rNCSS of the next day prior to AM dosing. The mean change from baseline in rNCSS (daily, AM, PM)was calculated as the subject's treatment period mean (over 14 days; from Day 0 PM to Day 14 AM) minus the baseline period (placebo run-in) mean.

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

End point timeframe:

Baseline to 14 days

| **End point values** | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 314 | 312 | | |
| Units: Score on scale | | | | |
| arithmetic mean (standard deviation) | -0.34 (± 0.547) | -0.2 (± 0.443) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: End-of-treatment Assessment of Response to Therapy for Ocular Symptoms

| End point title | End-of-treatment Assessment of Response to Therapy for Ocular Symptoms |
|---|---|

End point description:

Overall response to therapy assessment was done using a 7-point categorical scale in which participants rated their response to therapy as follows: +3 = Significantly Improved; +2 = Moderately Improved; +1 = Mildly Improved; 0 = No Change; -1= Mildly Worse; -2 = Moderately Worse; -3 = Significantly Worse.

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

End point timeframe:

Baseline to 14 days

| End point values | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 313 | 309 | | |
| Units: Participants | | | | |
| number (not applicable) | | | | |
| Significantly improved | 22 | 16 | | |
| Moderately improved | 76 | 59 | | |
| Mildly improved | 79 | 71 | | |
| No change | 81 | 97 | | |
| Mildly Worse | 21 | 20 | | |
| Moderately Worse | 24 | 24 | | |
| Significantly Worse | 10 | 22 | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Mean Change in Objective Assessment of Conjunctival Redness

| End point title | Mean Change in Objective Assessment of Conjunctival Redness |
|---|---|

End point description:

Conjunctival redness was evaluated as a clinical sign of SAR by the investigator. Scoring of severity was rated according to a 4-point scale: 0 = normal; 1 = Slightly pink; 2 = Moderately pink, some dilation; 3 = Intense red vessels, dilated.

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

End point timeframe:

Baseline to 14 days

| **End point values** | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 314 | 312 | | |
| Units: Score on scale | | | | |
| arithmetic mean (standard deviation) | -0.2 (± 0.815) | -0.15 (± 0.736) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Mean Changes From Baseline in Mini Rhinoconjunctivitis Quality of Life Questionnaire (MiniRQLQ) Scores

| End point title | Mean Changes From Baseline in Mini Rhinoconjunctivitis Quality of Life Questionnaire (MiniRQLQ) Scores |
|---|---|

End point description:

MiniRQLQ is a 14-item, disease-specific instrument for assessing the impact of allergic rhinitis on activities of daily living and overall well-being. It measures five domains of functional impairment that are most important to subjects with SAR: practical problems, nasal symptoms, eye symptoms, activity limitations, and other symptoms. Participants scored their degree of impairment on a seven-point scale. (0 - 6). Mini RQLQ final score is the average of sub-scales, ranges from 0 (best possible outcome) to 6 (worst possible outcome).

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

End point timeframe:

Baseline to 14 days

| **End point values** | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 314 | 311 | | |
| Units: Score on scale | | | | |
| arithmetic mean (standard deviation) | -0.98 (± 1.311) | -0.49 (± 1.091) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Activities

| End point title | Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Activities |
|---|---|

End point description:

MiniRQLQ is a 14-item, disease-specific instrument for assessing the impact of allergic rhinitis on activities of daily living and overall well-being. Activity limitations is one of the domains of Mini RQLQ scores. Participants scored their degree of impairment on a seven-point scale (0 = not troubled, 6 = extremely troubled).

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

End point timeframe:

Baseline to 14 days

| **End point values** | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 314 | 311 | | |
| Units: Score on scale | | | | |
| arithmetic mean (standard deviation) | -0.93 (± 1.384) | -0.39 (± 1.269) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Practical Problems

| End point title | Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Practical Problems |
|---|---|

End point description:

MiniRQLQ is a 14-item, disease-specific instrument for assessing the impact of allergic rhinitis on activities of daily living and overall well-being. Activity limitations is one of the domains of Mini RQLQ scores. Participants scored their degree of impairment on a seven-point scale (0 = not troubled, 6 = extremely troubled).

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

End point timeframe:

Baseline to 14 days

| **End point values** | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 314 | 311 | | |
| Units: Score on a scale | | | | |
| arithmetic mean (standard deviation) | -1.04 (± 1.476) | -0.57 (± 1.258) | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Nose Symptoms

| End point title | Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Nose Symptoms |
|---|---|

End point description:

MiniRQLQ is a 14-item, disease-specific instrument for assessing the impact of allergic rhinitis on activities of daily living and overall well-being. "Nose Symptoms" is one of the domains of Mini RQLQ scores. Participants scored their degree of impairment on a seven-point scale (0 = not troubled, 6 = extremely troubled).

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

End point timeframe:

Baseline to 14 days

| End point values | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 313 | 310 | | |
| Units: Score on scale | | | | |
| arithmetic mean (standard deviation) | -1.09 (± 1.456) | -0.5 (± 1.257) | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Eye Symptoms

| End point title | Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Eye Symptoms |
|---|---|

End point description:

MiniRQLQ is a 14-item, disease-specific instrument for assessing the impact of allergic rhinitis on activities of daily living and overall well-being. "Eye Symptoms" is one of the domains of Mini RQLQ scores. Participants scored their degree of impairment on a seven-point scale (0 = not troubled, 6 = extremely troubled).

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

End point timeframe:

Baseline to 14 days

| End point values | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 313 | 310 | | |
| Units: Score on a scale | | | | |
| arithmetic mean (standard deviation) | -0.98 (± 1.512) | -0.55 (± 1.284) | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Other Symptoms

| End point title | Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Other Symptoms |
|---|---|

End point description:

MiniRQLQ is a 14-item, disease-specific instrument for assessing the impact of allergic rhinitis on activities of daily living and overall well-being. "Other Symptoms" is one of the domains of Mini RQLQ scores. Participants scored their degree of impairment on a seven-point scale (0 = not troubled, 6 = extremely troubled).

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

End point timeframe:

Baseline to 14 days

| End point values | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 313 | 310 | | |
| Units: Score on a scale | | | | |
| arithmetic mean (standard deviation) | -0.89 (± 1.607) | -0.48 (± 1.294) | | |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

| Adverse events information | |
|---|---|
| Timeframe for reporting adverse events: | |
| Participants were followed for the duration of study, an average of 3 weeks | |
| Assessment type | Systematic |

| Dictionary used | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 15.1 |

| Reporting groups | |
|---|---|
| Reporting group title | Fluticasone Propionate Nasal Spray |
| Reporting group description: | |
| Two sprays of Fluticasone propionate nasal spray (50 mcg/spray) per nostril to be administered in morning (Total dose 200 mcg). | |
| Reporting group title | Placebo Nasal Spray |
| Reporting group description: | |
| Two sprays of placebo per nostril to be administered in morning. | |

| Serious adverse events | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 314 (0.00%) | 0 / 312 (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: 0.3 %

| Non-serious adverse events | Fluticasone Propionate Nasal Spray | Placebo Nasal Spray | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 8 / 314 (2.55%) | 8 / 312 (2.56%) | |
| Injury, poisoning and procedural complications | | | |
| Laceration | | | |
| subjects affected / exposed | 1 / 314 (0.32%) | 0 / 312 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 1 / 314 (0.32%) | 0 / 312 (0.00%) | |
| occurrences (all) | 1 | 0 | |

| | | | |
|---|---|---|---|
| Cardiac disorders | | | |
| Palpitations | | | |
| subjects affected / exposed | 1 / 314 (0.32%) | 0 / 312 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 2 / 314 (0.64%) | 0 / 312 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Migraine | | | |
| subjects affected / exposed | 0 / 314 (0.00%) | 1 / 312 (0.32%) | |
| occurrences (all) | 0 | 1 | |
| General disorders and administration site conditions | | | |
| Pain | | | |
| subjects affected / exposed | 0 / 314 (0.00%) | 1 / 312 (0.32%) | |
| occurrences (all) | 0 | 1 | |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 314 (0.32%) | 2 / 312 (0.64%) | |
| occurrences (all) | 1 | 2 | |
| Thrist | | | |
| subjects affected / exposed | 1 / 314 (0.32%) | 0 / 312 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Immune system disorders | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 314 (0.00%) | 1 / 312 (0.32%) | |
| occurrences (all) | 0 | 1 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 314 (0.00%) | 1 / 312 (0.32%) | |
| occurrences (all) | 0 | 1 | |
| Respiratory Tract Congestion | | | |
| subjects affected / exposed | 0 / 314 (0.00%) | 1 / 312 (0.32%) | |
| occurrences (all) | 0 | 1 | |
| Throat irritation | | | |
| subjects affected / exposed | 1 / 314 (0.32%) | 0 / 312 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Skin and subcutaneous tissue disorders | | | |

| | | | |
|---|---|---|---|
| Dermatitis | | | |
| subjects affected / exposed | 0 / 314 (0.00%) | 1 / 312 (0.32%) | |
| occurrences (all) | 0 | 1 | |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 314 (0.00%) | 2 / 312 (0.64%) | |
| occurrences (all) | 0 | 2 | |
| Gastrointestinal Viral | | | |
| subjects affected / exposed | 1 / 314 (0.32%) | 0 / 312 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Influenza | | | |
| subjects affected / exposed | 0 / 314 (0.00%) | 1 / 312 (0.32%) | |
| 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