



Clinical trial results:

A randomised, double-blind, placebo-controlled exploratory study to explore the efficacy and safety of PQ Grass 27600 SU in subjects with seasonal allergic rhinitis and/or rhinoconjunctivitis induced by grass pollen exposure

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2020-000408-13 |
| Trial protocol | DE |
| Global end of trial date | 28 October 2021 |

Results information

| | |
|--------------------------------|---------------|
| Result version number | v1 (current) |
| This version publication date | 28 March 2024 |
| First version publication date | 28 March 2024 |

Trial information

Trial identification

| | |
|-----------------------|------------|
| Sponsor protocol code | PQGrass309 |
|-----------------------|------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT04687059 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Allergy Therapeutics |
| Sponsor organisation address | Dominion Way, West Sussex, BN14 8SA, Worthing, United Kingdom, |
| Public contact | Clinical Research Management, Bencard Allergie GmbH, pqgrass309@allergytherapeutics.com |
| Scientific contact | Clinical Research Management, Bencard Allergie GmbH, pqgrass309@allergytherapeutics.com |

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 | 28 October 2021 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 28 October 2021 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To explore the efficacy of PQ Grass 27600 SU in grass pollen-induced seasonal allergic rhinitis and/or rhinoconjunctivitis in a field setting

Protection of trial subjects:

This study will be conducted by the investigator and the study centre in full conformance with the International Council for Harmonisation E6 guideline for GCP and the principles of the Declaration of Helsinki or the laws and regulations of the country in which the research is conducted, whichever affords the greater protection to the individual.

All subjects gave their written informed consent by personally dating and signing the ICF prior to admission to the clinical study and before any study protocol-specified procedures were carried out.

Background therapy: -

Evidence for comparator: -

| | |
|---|-----------------|
| Actual start date of recruitment | 19 October 2020 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Safety |
| Long term follow-up duration | 1 Years |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | Germany: 77 |
| Country: Number of subjects enrolled | United States: 42 |
| Worldwide total number of subjects | 119 |
| EEA total number of subjects | 77 |

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) | 119 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

The study was initiated on 19 October 2020 (first subject first visit [FSFV]) and the last subject last visit (LSLV).

Pre-assignment

Screening details:

196 screenings were performed, of these 193 subjects were screened as there were 3 re-screenings. Overall, 119 (100%) subjects (SAF/FAS) were randomised (77 subjects in Germany and 42 subjects in US).

Pre-assignment period milestones

| | |
|------------------------------|-----|
| Number of subjects started | 119 |
| Number of subjects completed | 119 |

Period 1

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

Arms

| | |
|--|--------------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | PQ Grass Conventional Dosing Regimen |
| Arm description: - | |
| Arm type | Experimental |
| Investigational medicinal product name | PQ Grass |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Subcutaneous use |
| Dosage and administration details: | |
| Cumulative dose 27600 SU | |
| Arm title | PQ Grass Extended Dosing Regimen |
| Arm description: - | |
| Arm type | Experimental |
| Investigational medicinal product name | PQ Grass |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Subcutaneous use |
| Dosage and administration details: | |
| Cumulative dose 27600 SU | |
| Arm title | Placebo (containing MCT) |
| Arm description: - | |
| Arm type | Placebo |

| | |
|--|--------------------------|
| Investigational medicinal product name | Placebo with MCT |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Placebo contained MCT contains 2% (w/v) L-tyrosine and 0.5% (w/v) phenol and was indistinguishable from the active treatment.

| | |
|------------------|-----------------------|
| Arm title | Placebo (without MCT) |
|------------------|-----------------------|

Arm description: -

| | |
|--|--------------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo with MCT |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Placebo without MCT contained a buffered saline solution with 0.5% (w/v) phenol. The solution was colourless in appearance and was easily distinguishable from the active treatment and the placebo containing MCT.

| Number of subjects in period 1 | PQ Grass Conventional Dosing Regimen | PQ Grass Extended Dosing Regimen | Placebo (containing MCT) |
|---------------------------------------|--------------------------------------|----------------------------------|--------------------------|
| Started | 41 | 40 | 20 |
| Completed | 41 | 40 | 20 |

| Number of subjects in period 1 | Placebo (without MCT) |
|---------------------------------------|-----------------------|
| Started | 18 |
| Completed | 18 |

Period 2

| | |
|------------------------------|-------------------------|
| Period 2 title | Overall |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator |

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|---|--------------------------------------|
| Arm title | PQ Grass Conventional Dosing Regimen |
| Arm description: - | |
| Arm type | Experimental |
| Investigational medicinal product name | PQ Grass |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Subcutaneous use |
| Dosage and administration details: | |
| Cumulative dose 27600 SU | |
| Arm title | PQ Grass Extended Dosing Regimen |
| Arm description: - | |
| Arm type | Experimental |
| Investigational medicinal product name | PQ Grass |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Subcutaneous use |
| Dosage and administration details: | |
| Cumulative dose 27600 SU | |
| Arm title | Placebo (containing MCT) |
| Arm description: - | |
| Arm type | Placebo |
| Investigational medicinal product name | Placebo with MCT |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Subcutaneous use |
| Dosage and administration details: | |
| Placebo contained MCT contains 2% (w/v) L-tyrosine and 0.5% (w/v) phenol and was indistinguishable from the active treatment. | |
| Arm title | Placebo (without MCT) |
| Arm description: - | |
| Arm type | Placebo |
| Investigational medicinal product name | Placebo with MCT |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Subcutaneous use |
| Dosage and administration details: | |
| Placebo without MCT contained a buffered saline solution with 0.5% (w/v) phenol. The solution was colourless in appearance and was easily distinguishable from the active treatment and the placebo containing MCT. | |

| Number of subjects in period 2 | PQ Grass Conventional Dosing Regimen | PQ Grass Extended Dosing Regimen | Placebo (containing MCT) |
|--------------------------------|--|-------------------------------------|-----------------------------|
| | | | |
| Started | 41 | 40 | 20 |
| Completed | 41 | 40 | 20 |

| Number of subjects in period 2 | Placebo (without MCT) |
|--------------------------------|--------------------------|
| Started | 18 |
| Completed | 18 |

Baseline characteristics

Reporting groups

| | |
|--------------------------------|--------------------------------------|
| Reporting group title | PQ Grass Conventional Dosing Regimen |
| Reporting group description: - | |
| Reporting group title | PQ Grass Extended Dosing Regimen |
| Reporting group description: - | |
| Reporting group title | Placebo (containing MCT) |
| Reporting group description: - | |
| Reporting group title | Placebo (without MCT) |
| Reporting group description: - | |

| Reporting group values | PQ Grass Conventional Dosing Regimen | PQ Grass Extended Dosing Regimen | Placebo (containing MCT) |
|-----------------------------------|--------------------------------------|----------------------------------|--------------------------|
| Number of subjects | 41 | 40 | 20 |
| Age categorical | | | |
| Units: Subjects | | | |
| Adults (18-64 years) | 41 | 40 | 20 |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 34.5 | 32.3 | 34.3 |
| standard deviation | ± 11.45 | ± 10.23 | ± 10.69 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 28 | 21 | 9 |
| Male | 13 | 19 | 11 |
| Ethnicity | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 1 | 1 | 0 |
| Not Hispanic or Latino | 40 | 39 | 20 |
| Race | | | |
| Units: Subjects | | | |
| White | 38 | 37 | 18 |
| Black or African American | 1 | 2 | 1 |
| Asian | 2 | 0 | 1 |
| Other | 0 | 1 | 0 |
| Alcohol consumption and frequency | | | |
| Units: Subjects | | | |
| Never | 10 | 13 | 3 |
| Currently | 30 | 26 | 16 |
| Previously | 1 | 1 | 1 |
| Smoking consumption and frequency | | | |
| Units: Subjects | | | |
| Never | 29 | 32 | 15 |
| Currently | 6 | 3 | 3 |
| Previously | 6 | 5 | 2 |

| | | | |
|--|--------------------|-------------------|-------------------|
| Height Units: centimetre arithmetic mean standard deviation | 170.86 ± 10.365 | 173.25 ± 9.072 | 174.20 ± 7.161 |
| Weight Units: kilogram(s) arithmetic mean standard deviation | 76.30 ± 15.092 | 77.71 ± 16.336 | 76.95 ± 18.903 |
| BMI Units: kilogram(s)/cubic metre arithmetic mean standard deviation | 26.11 ± 4.625 | 25.81 ± 4.696 | 25.15 ± 4.7441 |

| Reporting group values | Placebo (without MCT) | Total | |
|---|-----------------------|-------|--|
| Number of subjects | 18 | 119 | |
| Age categorical Units: Subjects | | | |
| Adults (18-64 years) | 18 | 119 | |
| Age continuous Units: years arithmetic mean standard deviation | 31.5 ± 13.79 | - | |
| Gender categorical Units: Subjects | | | |
| Female | 10 | 68 | |
| Male | 8 | 51 | |
| Ethnicity Units: Subjects | | | |
| Hispanic or Latino | 2 | 4 | |
| Not Hispanic or Latino | 16 | 115 | |
| Race Units: Subjects | | | |
| White | 15 | 108 | |
| Black or African American | 1 | 5 | |
| Asian | 0 | 3 | |
| Other | 2 | 3 | |
| Alcohol consumption and frequency Units: Subjects | | | |
| Never | 7 | 33 | |
| Currently | 11 | 83 | |
| Previously | 0 | 3 | |
| Smoking consumption and frequency Units: Subjects | | | |
| Never | 17 | 93 | |
| Currently | 0 | 12 | |
| Previously | 1 | 14 | |
| Height Units: centimetre arithmetic mean standard deviation | 171.59 ± 10.958 | - | |
| Weight | | | |

| | | | |
|--------------------------------|--------------|---|--|
| Units: kilogram(s) | | | |
| arithmetic mean | 74.71 | | |
| standard deviation | ± 11.815 | - | |
| BMI | | | |
| Units: kilogram(s)/cubic metre | | | |
| arithmetic mean | 25.38 | | |
| standard deviation | ± 3.251 | - | |

End points

End points reporting groups

| | |
|---|--------------------------------------|
| Reporting group title | PQ Grass Conventional Dosing Regimen |
| Reporting group description: - | |
| Reporting group title | PQ Grass Extended Dosing Regimen |
| Reporting group description: - | |
| Reporting group title | Placebo (containing MCT) |
| Reporting group description: - | |
| Reporting group title | Placebo (without MCT) |
| Reporting group description: - | |
| Reporting group title | PQ Grass Conventional Dosing Regimen |
| Reporting group description: - | |
| Reporting group title | PQ Grass Extended Dosing Regimen |
| Reporting group description: - | |
| Reporting group title | Placebo (containing MCT) |
| Reporting group description: - | |
| Reporting group title | Placebo (without MCT) |
| Reporting group description: - | |
| Subject analysis set title | FAS |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| All subjects who received at least 1 injection of the IMP. The analysis followed the intention-to-treat principle and analysed subjects according to the treatment group to which they were randomised. | |
| Subject analysis set title | SAF |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: | |
| All subjects who received at least 1 injection of the IMP. Subjects were analysed according to the treatment that they actually received. | |

Primary: CSMS Averaged Over the Peak GPS

| | |
|---|---------------------------------|
| End point title | CSMS Averaged Over the Peak GPS |
| End point description: | |
| 6 individual symptoms assessed in a 4 point severity scale (0-No symptoms to 3-Severe symptoms. | |
| End point type | Primary |
| End point timeframe: | |
| Approximately 2-5 weeks | |

| End point values | PQ Grass Conventional Dosing Regimen | PQ Grass Extended Dosing Regimen | Placebo (containing MCT) | |
|-------------------------------------|--------------------------------------|----------------------------------|--------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 41 | 40 | 20 | |
| Units: Points | | | | |
| least squares mean (standard error) | 0.56 (± 0.263) | 0.67 (± 0.264) | 0 (± 0) | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | PQ Grass Conventional vs. Placebo containing MCT |
| Comparison groups | PQ Grass Conventional Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 61 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0325 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -33.1 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -48.8 |
| upper limit | -17.4 |

| | |
|---|---|
| Statistical analysis title | PQ Grass Extended vs Placebo containing MCT |
| Comparison groups | PQ Grass Extended Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0112 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -39.5 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -54.7 |
| upper limit | -24.4 |

Secondary: CSMS Averaged Over the Entire (or Truncated) GPS

| | |
|------------------------|--|
| End point title | CSMS Averaged Over the Entire (or Truncated) GPS |
| End point description: | 6 individual symptoms assessed in a 4 point severity scale (0-No symptoms to 3-Severe symptoms). |
| End point type | Secondary |
| End point timeframe: | |
| Approximately 10 weeks | |

| End point values | PQ Grass Conventional Dosing Regimen | PQ Grass Extended Dosing Regimen | Placebo (containing MCT) | |
|-------------------------------------|--------------------------------------|----------------------------------|--------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 41 | 40 | 20 | |
| Units: Points | | | | |
| least squares mean (standard error) | 0.32 (± 0.25) | 0.5 (± 0.215) | 0 (± 0) | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | PQ Grass Conventional vs. Placebo containing MCT |
| Comparison groups | PQ Grass Conventional Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 61 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1314 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -25.1 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -43.3 |
| upper limit | -6.8 |

| | |
|---|---|
| Statistical analysis title | PQ Grass Extended vs Placebo containing MCT |
| Comparison groups | PQ Grass Extended Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0197 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -38.8 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -55.8 |
| upper limit | -21.7 |

Secondary: TCS Averaged Over the Peak GPS

| | |
|---|--------------------------------|
| End point title | TCS Averaged Over the Peak GPS |
| End point description: 6 individual symptoms in a similar fashion to CSMS assessed in a 4 point severity scale (0-No symptoms to 3-Severe symptoms). | |
| End point type | Secondary |
| End point timeframe: Approximately 2-5 weeks | |

| End point values | PQ Grass Conventional Dosing Regimen | PQ Grass Extended Dosing Regimen | Placebo (containing MCT) | |
|-------------------------------------|--------------------------------------|----------------------------------|--------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 41 | 40 | 20 | |
| Units: Points | | | | |
| least squares mean (standard error) | 3.8 (\pm 1.748) | 4.42 (\pm 1.759) | 0 (\pm 0) | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | PQ Grass Conventional vs. Placebo containing MCT |
| Comparison groups | PQ Grass Conventional Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 61 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0298 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -35 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -51.2 |
| upper limit | -18.9 |

| | |
|----------------------------|---|
| Statistical analysis title | PQ Grass Extended vs Placebo containing MCT |
| Comparison groups | PQ Grass Extended Dosing Regimen v Placebo (containing MCT) |

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.012 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -40.8 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -56.4 |
| upper limit | -25.1 |

Secondary: TCS Averaged Over Entire (or Truncated) GPS

| | |
|------------------------|--|
| End point title | TCS Averaged Over Entire (or Truncated) GPS |
| End point description: | 6 individual symptoms in a similar fashion to CSMS assessed in a 4 point severity scale (0-No symptoms to 3-Severe symptoms) |
| End point type | Secondary |
| End point timeframe: | Approximately 10 weeks |

| End point values | PQ Grass Conventional Dosing Regimen | PQ Grass Extended Dosing Regimen | Placebo (containing MCT) | |
|-------------------------------------|--------------------------------------|----------------------------------|--------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 41 | 40 | 20 | |
| Units: Points | | | | |
| least squares mean (standard error) | 2.23 (± 1.416) | 3.29 (± 1.418) | 0 (± 0) | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | PQ Grass Conventional vs. Placebo containing MCT |
| Comparison groups | PQ Grass Conventional Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 61 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1158 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -26.9 |

| | |
|---------------------|-------------|
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -45.6 |
| upper limit | -8.2 |

| | |
|---|---|
| Statistical analysis title | PQ Grass Extended vs Placebo containing MCT |
| Comparison groups | PQ Grass Extended Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0202 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -39.9 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -57.5 |
| upper limit | -22.2 |

Secondary: Daily Symptom Score (dSS) of the CSMS Averaged Over the Peak and Entire (or truncated) GPS

| | |
|--|--|
| End point title | Daily Symptom Score (dSS) of the CSMS Averaged Over the Peak and Entire (or truncated) GPS |
| End point description: Sum of the scores (0-No symptoms to 3-Severe symptoms) for the 6 individual symptoms assessed in CSMS divided by 6. | |
| End point type | Secondary |
| End point timeframe: Approximately 10 weeks. Duration of the Peak Grass pollen season (GPS) to be determined as per pollen counts within the GPS. | |

| End point values | PQ Grass Conventional Dosing Regimen | PQ Grass Extended Dosing Regimen | Placebo (containing MCT) | |
|-------------------------------------|--------------------------------------|----------------------------------|--------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 41 | 40 | 20 | |
| Units: Points | | | | |
| least squares mean (standard error) | | | | |
| CSMS-dSS over the peak GPS | 0.27 (± 0.150) | 0.30 (± 0.151) | 0 (± 0) | |
| CSMS-dSS during entire GPS | 0.2 (± 0.128) | 0.26 (± 0.129) | 0 (± 0) | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | CSMS-dSS averaged over the peak GPS |
| Comparison groups | Placebo (containing MCT) v PQ Grass Conventional Dosing Regimen |
| Number of subjects included in analysis | 61 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0474 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -29.2 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -44.7 |
| upper limit | -13.7 |

| | |
|---|---|
| Statistical analysis title | CSMS-dSS averaged over the entire GPS |
| Comparison groups | PQ Grass Extended Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0415 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -31.2 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -47.9 |
| upper limit | -14.6 |

Secondary: Daily Medication Score (dMS) of the CSMS Averaged Over the Peak and Entire (or Truncated) GPS

| | |
|-----------------|---|
| End point title | Daily Medication Score (dMS) of the CSMS Averaged Over the Peak and Entire (or Truncated) GPS |
|-----------------|---|

End point description:

Score 0 (no relief medication) to 3 (highest step relief medication) per day; based on at least 1 dose of the medication of the highest step taken that day.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Approximately 10 weeks. Duration of the peak GPS to be determined as per pollen counts within the GPS. | |

| End point values | PQ Grass Conventional Dosing Regimen | PQ Grass Extended Dosing Regimen | Placebo (containing MCT) | |
|-------------------------------------|--------------------------------------|----------------------------------|--------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 41 | 40 | 20 | |
| Units: Points | | | | |
| least squares mean (standard error) | | | | |
| CSMS-dMS over peak GPS | 0.29 (± 1.41) | 0.37 (± 0.142) | 0 (± 0) | |
| CSMS-dMS during entire GPS | 0.13 (± 0.112) | 0.24 (± 0.112) | 0 (± 0) | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | CSMS-dMS averaged over the peak GPS |
| Comparison groups | PQ Grass Extended Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0089 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -55.3 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -74 |
| upper limit | -36.7 |

| | |
|---|---|
| Statistical analysis title | CSMS-dMS averaged over the entire (truncated) GPS |
| Comparison groups | PQ Grass Extended Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0316 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -53.5 |

| | |
|---------------------|-------------|
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -75.6 |
| upper limit | -31.4 |

Secondary: dSS of the TCS Averaged Over the Peak GPS and Entire (or Truncated) GPS

| | |
|-----------------|---|
| End point title | dSS of the TCS Averaged Over the Peak GPS and Entire (or Truncated) GPS |
|-----------------|---|

End point description:

Sum of the scores (0-No symptoms to 3-Severe symptoms) for the 6 individual symptoms (i.e. ranging from 0 to 18).

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

End point timeframe:

Approximately 10 weeks. Duration of the Peak Grass pollen season (GPS) to be determined as per pollen counts within the GPS.

| End point values | PQ Grass Conventional Dosing Regimen | PQ Grass Extended Dosing Regimen | Placebo (containing MCT) | |
|-------------------------------------|--------------------------------------|----------------------------------|--------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 41 | 40 | 20 | |
| Units: Points | | | | |
| least squares mean (standard error) | | | | |
| TCS-dSS over the peak GPS | 1.62 (± 0.903) | 1.84 (± 0.908) | 0 (± 0) | |
| TCS-dSS during the entire GPS | 1.21 (± 0.774) | 1.60 (± 0.777) | 0 (± 0) | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | TCS-dSS averaged over the peak GPS |
| Comparison groups | PQ Grass Extended Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0426 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -29.6 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -44.9 |
| upper limit | -14.3 |

| | |
|---|---|
| Statistical analysis title | TCS-dSS averaged during the entire (truncated) GPS |
| Comparison groups | PQ Grass Extended Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0396 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -31.3 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -47.8 |
| upper limit | -14.8 |

Secondary: dMS of the TCS Averaged Over the Peak GPS and Entire (or Truncated) GPS

| | |
|--|---|
| End point title | dMS of the TCS Averaged Over the Peak GPS and Entire (or Truncated) GPS |
| End point description: Score 0 (no relief medication) to 3 (highest step relief medication) per day; based on at least 1 dose of the medication of the highest step taken that day. | |
| End point type | Secondary |
| End point timeframe: Approximately 10 weeks. Duration of the Peak Grass pollen season (GPS) to be determined as per pollen counts within the GPS. | |

| End point values | PQ Grass Conventional Dosing Regimen | PQ Grass Extended Dosing Regimen | Placebo (containing MCT) | |
|-------------------------------------|--------------------------------------|----------------------------------|--------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 41 | 40 | 20 | |
| Units: Points | | | | |
| least squares mean (standard error) | | | | |
| TCS-dMS over the peak GPS | 2.18 (± 1.025) | 2.58 (± 1.034) | 0 (± 0) | |
| TCS-dMS during the entire GPS | 1.02 (± 0.798) | 1.70 (± 0.797) | 0 (± 0) | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | TCS-dMS averaged over the peak GPS |
| Comparison groups | PQ Grass Extended Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0127 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -55.8 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -75.4 |
| upper limit | -36.2 |

| | |
|---|---|
| Statistical analysis title | TCS-dMS averaged over the entire (truncated) GPS |
| Comparison groups | PQ Grass Extended Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0326 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -54.2 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -77.3 |
| upper limit | -31.1 |

Secondary: The Probability of Well Days and Severe Days During the Peak and Entire (or Truncated) GPS

| | |
|--|--|
| End point title | The Probability of Well Days and Severe Days During the Peak and Entire (or Truncated) GPS |
| End point description: | |
| <p>A "well day" was defined based on CSMS as a day with:</p> <ul style="list-style-type: none"> • No use of relief medication on the particular day, • And a total symptom score ≤ 2 out of 18 <p>A "severe day" was based on CSMS and defined as a day with a symptom score of 3 in any of the 6 rhinitis/rhinoconjunctivitis symptoms.</p> <p>The probability of a well day or a severe day was analyzed using data on a by-day level per subject using generalized estimating equation (GEE) or similar approaches as appropriate.</p> <p>Well days and severe days were assessed during the peak GPS and entire (or truncated) GPS</p> | |
| End point type | Secondary |
| End point timeframe: | |
| Approximately 10 weeks. | |

| End point values | PQ Grass Conventional Dosing Regimen | PQ Grass Extended Dosing Regimen | Placebo (containing MCT) | |
|---|---|---|--------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 41 | 37 | 19 | |
| Units: day | | | | |
| arithmetic mean (standard deviation) | | | | |
| Number of well days during peak GPS | 4.73 (± 6.693) | 6.46 (± 6.539) | 0 (± 0) | |
| Number of severe days during peak GPS | 2.07 (± 4.491) | 1.03 (± 1.818) | 0 (± 0) | |
| Number of well days during entire GPS | 20.10 (± 18.195) | 25.03 (± 17.716) | 0 (± 0) | |
| Number of severe days during entire GPS | 5.39 (± 12.870) | 2.76 (± 4.044) | 0 (± 0) | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Number of well days during the peak GPS |
| Comparison groups | PQ Grass Extended Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 56 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.86 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | 0.958 |
| upper limit | 3.612 |

| | |
|---|---|
| Statistical analysis title | Number of severe days during the peak GPS |
| Comparison groups | PQ Grass Extended Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 56 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.31 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | 0.158 |
| upper limit | 0.607 |

Secondary: Serum Ig Responses (Total IgE; Grass-specific IgE and IgG4; Specific IgE/Total IgE and Specific IgE/Specific IgG4) at Visit 12 and Visit 15

| | |
|-----------------|---|
| End point title | Serum Ig Responses (Total IgE; Grass-specific IgE and IgG4; Specific IgE/Total IgE and Specific IgE/Specific IgG4) at Visit 12 and Visit 15 |
|-----------------|---|

End point description:

Immunological measurements (total IgE, grass-specific IgE and IgG4, specific IgE/total IgE and specific IgE/specific IgG4) and their changes between screening and post-treatment were analyzed descriptively. The change from baseline in immunoglobulin measurements was additionally analyzed using analysis of covariance (ANCOVA), including treatment groups and with baseline as covariate.

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

End point timeframe:

Approximately 10 week

| End point values | PQ Grass Conventional Dosing Regimen | PQ Grass Extended Dosing Regimen | Placebo (containing MCT) | |
|--|--------------------------------------|----------------------------------|--------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 37 | 38 | 20 | |
| Units: unit(s) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Serum total IgE [kU/L] - Visit 12 | 13.31 (± 28.903) | 3.14 (± 28.518) | -102.19 (± 39.327) | |
| Serum total IgE [kU/L] - Visit 15 | 40.86 (± 17.750) | 27.53 (± 17.286) | -6.78 (± 24.155) | |
| Serum grass-specific IgE [kU/L] - Visit 12 | 9.24 (± 4.012) | 9.24 (± 3.995) | -7.24 (± 4.860) | |
| Serum grass-specific IgE [kU/L] - Visit 15 | 18.66 (± 3.312) | 17.96 (± 3.330) | 11.36 (± 4.449) | |
| Serum grass-specific IgG4 [mg/L] - Visit 12 | 2.76 (± 0.673) | 3.50 (± 0.670) | 0.15 (± 0.871) | |
| Serum grass-specific IgG4 [mg/L] - Visit 15 | 1.93 (± 0.340) | 2.04 (± 0.339) | 0.33 (± 0.456) | |
| Grass-specific IgE / total IgE - Visit 12 | 0.04 (± 0.018) | 0.04 (± 0.017) | 0.01 (± 0.023) | |
| Grass-specific IgE / total IgE - Visit 15 | 0.10 (± 0.018) | 0.09 (± 0.018) | 0.09 (± 0.024) | |
| Grass-specific IgE / grass-specific IgG4 -Visit 12 | -39.09 (± 7.658) | -39.17 (± 7.641) | -1.58 (± 10.107) | |
| Grass-specific IgE / grass-specific IgG4 -Visit 15 | -22.72 (± 7.606) | -24.67 (± 7.602) | -7.19 (± 9.533) | |

Statistical analyses

| | |
|----------------------------|---|
| Statistical analysis title | Change from baseline to Visit 12 of serum IgG4 |
| Comparison groups | PQ Grass Extended Dosing Regimen v Placebo (containing MCT) |

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 58 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0006 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 3.34 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | 2.12 |
| upper limit | 4.56 |

| | |
|---|---|
| Statistical analysis title | Change from baseline to Visit 15 of IgG4 |
| Comparison groups | Placebo (containing MCT) v PQ Grass Conventional Dosing Regimen |
| Number of subjects included in analysis | 57 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0033 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 1.71 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | 0.98 |
| upper limit | 2.45 |

Secondary: RQLQ(S) During the Peak GPS

| | |
|------------------------|-----------------------------|
| End point title | RQLQ(S) During the Peak GPS |
| End point description: | |
| | |
| End point type | Secondary |
| End point timeframe: | |
| Approximately 10 weeks | |

| End point values | PQ Grass Conventional Dosing Regimen | PQ Grass Extended Dosing Regimen | Placebo (containing MCT) | |
|-------------------------------------|--------------------------------------|----------------------------------|--------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 28 | 30 | 13 | |
| Units: points | | | | |
| least squares mean (standard error) | | | | |

| | | | | |
|----------------------|---------------------|---------------------|--------------|--|
| RQLQ during peak GPS | 0.44 (\pm 0.316) | 0.72 (\pm 0.314) | 0 (\pm 0) | |
|----------------------|---------------------|---------------------|--------------|--|

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Extended vs. Placebo with MCT during peak GPS |
| Comparison groups | Placebo (containing MCT) v PQ Grass Extended Dosing Regimen |
| Number of subjects included in analysis | 43 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0243 |
| Method | Mixed models analysis |
| Parameter estimate | Median difference (final values) |
| Point estimate | -37.9 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -54.9 |
| upper limit | -21.8 |

| | |
|---|---|
| Statistical analysis title | Conventional vs Placebo with MCT during peak GPS |
| Comparison groups | PQ Grass Extended Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 43 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1706 |
| Method | Mixed models analysis |
| Parameter estimate | Median difference (final values) |
| Point estimate | -22.9 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -41.1 |
| upper limit | -4.7 |

Secondary: aTCS Average During GPS

| | |
|-------------------------|-------------------------|
| End point title | aTCS Average During GPS |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| Approximately 2-5 weeks | |

| End point values | PQ Grass Conventional Dosing Regimen | PQ Grass Extended Dosing Regimen | Placebo (containing MCT) | |
|---|---|---|--------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 41 | 40 | 20 | |
| Units: Points | | | | |
| least squares mean (standard deviation) | | | | |
| aTCS during peak GPS | 3.98 (± 1.839) | 4.63 (± 1.849) | 0 (± 0) | |
| aTCS during entire GPS | 2.36 (± 1.493) | 3.47 (± 1.496) | 0 (± 0) | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | aTCS average during peak GPS |
| Comparison groups | PQ Grass Extended Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0124 |
| Method | Mixed models analysis |
| Parameter estimate | Median difference (final values) |
| Point estimate | -40.1 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -55.6 |
| upper limit | -24.5 |

| | |
|---|---|
| Statistical analysis title | aTCS average during entire GPS |
| Comparison groups | PQ Grass Extended Dosing Regimen v Placebo (containing MCT) |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.023 |
| Method | Mixed models analysis |
| Parameter estimate | Median difference (final values) |
| Point estimate | -39.3 |
| Confidence interval | |
| level | Other: 80 % |
| sides | 2-sided |
| lower limit | -56.8 |
| upper limit | -21.8 |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

375 days (study duration including safety follow-up)

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 24.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|----------------------------------|
| Reporting group title | PQ Grass Standard Dosing Regimen |
|-----------------------|----------------------------------|

Reporting group description: -

| | |
|-----------------------|----------------------------------|
| Reporting group title | PQ Grass Extended Dosing Regimen |
|-----------------------|----------------------------------|

Reporting group description: -

| | |
|-----------------------|------------------|
| Reporting group title | Placebo with MCT |
|-----------------------|------------------|

Reporting group description: -

| | |
|-----------------------|---------------------|
| Reporting group title | Placebo without MCT |
|-----------------------|---------------------|

Reporting group description: -

| Serious adverse events | PQ Grass Standard Dosing Regimen | PQ Grass Extended Dosing Regimen | Placebo with MCT |
|---|----------------------------------|----------------------------------|------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 40 (0.00%) | 1 / 21 (4.76%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 40 (0.00%) | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 40 (0.00%) | 1 / 21 (4.76%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | Placebo without MCT | | |
|---|---------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from | 0 | | |

| | | | |
|---|----------------|--|--|
| adverse events | | | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| Non-serious adverse events | PQ Grass Standard Dosing Regimen | PQ Grass Extended Dosing Regimen | Placebo with MCT |
|---|----------------------------------|----------------------------------|-------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 39 / 40 (97.50%) | 38 / 40 (95.00%) | 21 / 21 (100.00%) |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 3 / 40 (7.50%) | 2 / 21 (9.52%) |
| occurrences (all) | 1 | 3 | 5 |
| General disorders and administration site conditions | | | |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 40 (0.00%) | 3 / 21 (14.29%) |
| occurrences (all) | 0 | 0 | 3 |
| Injection site erythema | | | |
| subjects affected / exposed | 31 / 40 (77.50%) | 35 / 40 (87.50%) | 2 / 21 (9.52%) |
| occurrences (all) | 109 | 126 | 3 |
| Injection site pain | | | |
| subjects affected / exposed | 21 / 40 (52.50%) | 19 / 40 (47.50%) | 8 / 21 (38.10%) |
| occurrences (all) | 48 | 48 | 18 |
| Injection site pruritus | | | |
| subjects affected / exposed | 23 / 40 (57.50%) | 29 / 40 (72.50%) | 2 / 21 (9.52%) |
| occurrences (all) | 82 | 93 | 3 |
| Injection site swelling | | | |

| | | | |
|---|------------------------|-------------------------|----------------------|
| subjects affected / exposed occurrences (all) | 28 / 40 (70.00%) 78 | 30 / 40 (75.00%) 102 | 3 / 21 (14.29%) 4 |
| Injection site urticaria subjects affected / exposed occurrences (all) | 10 / 40 (25.00%) 32 | 9 / 40 (22.50%) 29 | 1 / 21 (4.76%) 1 |
| Injection site warmth subjects affected / exposed occurrences (all) | 3 / 40 (7.50%) 3 | 5 / 40 (12.50%) 6 | 0 / 21 (0.00%) 0 |
| Eye disorders Eye pruritus subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 3 / 40 (7.50%) 4 | 3 / 21 (14.29%) 5 |
| Lacrimation increased subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 4 / 40 (10.00%) 4 | 0 / 21 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Nasal congestion subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 1 / 40 (2.50%) 1 | 4 / 21 (19.05%) 8 |
| Sneezing subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 2 | 4 / 40 (10.00%) 5 | 1 / 21 (4.76%) 2 |
| Infections and infestations COVID-19 subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 1 / 40 (2.50%) 1 | 2 / 21 (9.52%) 2 |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 4 / 40 (10.00%) 4 | 3 / 40 (7.50%) 3 | 1 / 21 (4.76%) 1 |

| | | | |
|--|----------------------|--|--|
| Non-serious adverse events | Placebo without MCT | | |
| Total subjects affected by non-serious adverse events subjects affected / exposed | 18 / 18 (100.00%) | | |
| Nervous system disorders Headache subjects affected / exposed occurrences (all) | 2 / 18 (11.11%) 2 | | |

| | | | |
|--|----------------------|--|--|
| General disorders and administration site conditions | | | |
| Injection site bruising subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | | |
| Injection site erythema subjects affected / exposed occurrences (all) | 4 / 18 (22.22%) 6 | | |
| Injection site pain subjects affected / exposed occurrences (all) | 2 / 18 (11.11%) 9 | | |
| Injection site pruritus subjects affected / exposed occurrences (all) | 2 / 18 (11.11%) 3 | | |
| Injection site swelling subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | | |
| Injection site urticaria subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | | |
| Injection site warmth subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | | |
| Eye disorders | | | |
| Eye pruritus subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 2 | | |
| Lacrimation increased subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Nasal congestion subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 2 | | |
| Sneezing subjects affected / exposed occurrences (all) | 2 / 18 (11.11%) 2 | | |

| | | | |
|--|---|--|--|
| Infections and infestations COVID-19 subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) | 3 / 18 (16.67%) 3 0 / 18 (0.00%) 0 | | |
|--|---|--|--|

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