# Clinical trial results:
# BURAN: Effects of BenralizUmab on AiRwAy DyNamics in Severe Eosinophilic Asthma using Functional Respiratory Imaging Parameters

## Summary

| | |
|---|---|
| EudraCT number | 2022-000152-11 |
| Trial protocol | BE ES PT FR |
| Global end of trial date | 19 July 2024 |

**Results information**

| | |
|---|---|
| Result version number | v2 (current) |
| This version publication date | 20 April 2025 |
| First version publication date | 20 March 2025 |
| Version creation reason | |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | D3250R00107 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT05552508 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | AstraZeneca |
| Sponsor organisation address | Sodertalje, Sodertalje, Sweden, 15185 |
| Public contact | Global Clinical Lead, AstraZeneca, +1 877-240-9479, information.center@astrazeneca.com |
| Scientific contact | Global Clinical Lead, AstraZeneca, +1 877-240-9479, information.center@astrazeneca.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 | 06 September 2024 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 19 July 2024 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The main objective of this study was to describe the change from baseline in airway dynamics after 13 weeks following treatment with benralizumab, using total mucus volume measurements from untrimmed airways.

Protection of trial subjects:

This study was performed in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that were
consistent with International Council of Harmonization (ICH)/Good Clinical Practice (GCP), applicable regulatory requirements and
the AstraZeneca policy on Bioethics.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 11 October 2022 |
| 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 | Belgium: 6 |
| Country: Number of subjects enrolled | France: 1 |
| Country: Number of subjects enrolled | Portugal: 5 |
| Country: Number of subjects enrolled | Spain: 25 |
| Country: Number of subjects enrolled | United Kingdom: 2 |
| Country: Number of subjects enrolled | United States: 6 |
| Worldwide total number of subjects | 45 |
| EEA total number of subjects | 37 |

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) | 36 |
| From 65 to 84 years | 9 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

This study was conducted between 11 October 2022 to 19 July 2024 at 24 study centers.

### Pre-assignment

Screening details:

Participants who met the inclusion criteria and none of the exclusion criteria were enrolled to the study. Informed Consent Form (ICF) was signed prior of screening procedures. All study assessments were performed as per the Schedule of Activities.

### Period 1

| | |
|---|---|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

### Arms

| | |
|---|---|
| **Arm title** | Benralizumab |

Arm description:

Participants received 3 doses of benralizumab 30 milligrams (mg) as subcutaneous injection once every 4 weeks (Week 0, Week 4, and Week 8).

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Benralizumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Concentrate for solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Participants received 3 doses of benralizumab 30 mg as subcutaneous injection once every 4 weeks (Week 0, Week 4, and Week 8).

| **Number of subjects in period 1** | Benralizumab |
|---|---|
| Started | 45 |
| Completed | 42 |
| Not completed | 3 |
| Adverse event, non-fatal | 3 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Benralizumab |
| Reporting group description: | |
| Participants received 3 doses of benralizumab 30 milligrams (mg) as subcutaneous injection once every 4 weeks (Week 0, Week 4, and Week 8). | |

| Reporting group values | Benralizumab | Total | |
|---|---|---|---|
| Number of subjects | 45 | 45 | |
| Age categorical<br>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) | 36 | 36 | |
| From 65-84 years | 9 | 9 | |
| 85 years and over | 0 | 0 | |
| Age Continuous<br>Units: Years | | | |
| arithmetic mean | 53.4 | | |
| standard deviation | ± 12.4 | - | |
| Sex: Female, Male<br>Units: Participants | | | |
| Female | 28 | 28 | |
| Male | 17 | 17 | |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 6 | 6 | |
| Not Hispanic or Latino | 39 | 39 | |
| Unknown or Not Reported | 0 | 0 | |

## End points

### End points reporting groups

| Reporting group title | Benralizumab |
|---|---|

Reporting group description:

Participants received 3 doses of benralizumab 30 milligrams (mg) as subcutaneous injection once every 4 weeks (Week 0, Week 4, and Week 8).

### Primary: Change from baseline in untrimmed total mucus volume at total lung capacity (TLC)

| End point title | Change from baseline in untrimmed total mucus volume at total lung capacity (TLC)[1] |
|---|---|

End point description:

Change from baseline in airway dynamics after 13 weeks following treatment with benralizumab, using total mucus volume (specific airway volume) at TLC measurements from untrimmed airways was assessed.
Primary analysis population set consisted portion of the evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during the study period where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13.

| End point type | Primary |
|---|---|

End point timeframe:

Baseline and Week 13

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The statistical analysis was not included due to tool constraint.

| End point values | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 39 | | | |
| Units: Milliliters (mL) | | | | |
| arithmetic mean (standard deviation) | | | | |
| All participants (n= 39) | -0.1279 (± 0.4199) | | | |
| Participants with >=4 mucus plugs (n= 27) | -0.1822 (± 0.4977) | | | |
| Participants with <4 mucus plugs (n= 12) | -0.0056 (± 0.0111) | | | |
| OCS-dependent participants (n= 2) | -0.1619 (± 0.4627) | | | |
| Non-OCS-dependent participants (n= 37) | -0.1260 (± 0.4244) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from baseline in untrimmed total mucus plugs score at TLC

| End point title | Change from baseline in untrimmed total mucus plugs score at |
|---|---|

| | |
|---|---|
| | TLC |

End point description:

Mucus plugs was scored with a scoring system similar to that by Dunican et al. with the Severe Asthma Research Program (SARP) based on bronchopulmonary segmental (BS) anatomy. Mucus score was calculated by counting the number of BS which contained 1 or more mucus plug, up to a maximum score of 18 related to the 18 BS present. Here, a mucus plug is defined as complete occlusion of the airway visible at TLC. Each BS is given a score of 1 (mucus plug present) or 0 (mucus plug absent). The segment scores of each lobe are summed to generate a total mucus score for both lungs, where mucus score ranging from 0-18. Higher scores = worse outcome. Primary analysis population set consisted portion of evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during study period where evaluable population was defined as those who completed three doses of study intervention and had measurements of outcome at both baseline and Week 13.

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

End point timeframe:

Baseline and Week 13

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 39 | | | |
| Units: Score on a scale | | | | |
| arithmetic mean (standard deviation) | -11.0 (± 32.8) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from baseline in untrimmed total air trapping at functional residual capacity (FRC)

| | |
|---|---|
| End point title | Change from baseline in untrimmed total air trapping at functional residual capacity (FRC) |

End point description:

Change from baseline in untrimmed total air trapping at FRC was assessed.
Primary analysis population set consisted portion of the evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during the study period where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13.

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

End point timeframe:

Baseline and Week 13

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 34 | | | |
| Units: Percentage of air trapping | | | | |
| arithmetic mean (standard deviation) | -0.1410 (± 12.1660) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from baseline in trimmed distal airway wall volume at TLC

| End point title | Change from baseline in trimmed distal airway wall volume at TLC |
|---|---|

End point description:

Change from baseline in trimmed distal airway wall volume at TLC was assessed. Change from baseline in airway dynamics at Week 13 following treatment with benralizumab as measured by secondary functional respiratory imaging (FRI) endpoints, irrespective of participants characteristics was assessed. Primary analysis population set consisted portion of the evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during the study period where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13 where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13.

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

End point timeframe:

Baseline and Week 13

| End point values | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 39 | | | |
| Units: mL | | | | |
| arithmetic mean (standard deviation) | -0.9386 (± 6.1359) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from baseline in untrimmed distal airway volume at TLC

| End point title | Change from baseline in untrimmed distal airway volume at TLC |
|---|---|

End point description:

Change from baseline in untrimmed distal airway volume at TLC was assessed.
Primary analysis population set consisted portion of the evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during the study period where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13 where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13.

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

End point timeframe:

Baseline and Week 13

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 39 | | | |
| Units: mL | | | | |
| arithmetic mean (standard deviation) | 1.1225 (± 4.5836) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from baseline in untrimmed distal airway volume at FRC

| End point title | Change from baseline in untrimmed distal airway volume at FRC |
|---|---|

End point description:

Change from baseline in untrimmed distal airway volume at FRC was assessed.
Primary analysis population set consisted portion of the evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during the study period where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13.

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

End point timeframe:

Baseline and Week 13

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 34 | | | |
| Units: mL | | | | |
| arithmetic mean (standard deviation) | 0.5079 (± 1.9741) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from baseline in untrimmed total lung volume at TLC

| End point title | Change from baseline in untrimmed total lung volume at TLC |
|---|---|

End point description:

Change from baseline in untrimmed total lung volume at TLC was assessed.
Primary analysis population set consisted portion of the evaluable population that did not have any

acute asthma exacerbation nor lower respiratory tract infection during the study period where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13.

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

End point timeframe:

Baseline and Week 13

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 39 | | | |
| Units: Liters (L) | | | | |
| arithmetic mean (standard deviation) | 0.0287 (± 0.4416) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change from baseline in untrimmed total lung volume at FRC

| End point title | Change from baseline in untrimmed total lung volume at FRC |
|---|---|

End point description:

Change from baseline in untrimmed total lung volume at FRC was assessed.
Primary analysis population set consisted portion of the evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during the study period where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13.

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

End point timeframe:

Baseline and Week 13

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 34 | | | |
| Units: Liters (L) | | | | |
| arithmetic mean (standard deviation) | -0.0275 (± 0.5101) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Correlation between untrimmed total air trapping at FRC and pre-BD FEV1

| End point title | Correlation between untrimmed total air trapping at FRC and pre-BD FEV1 |
|---|---|

End point description:

The relationship between airway dynamics and conventional lung function measurements, cross sectionally (at Week 0) and irrespective of participants characteristics was assessed. Positive correlations were identified by values greater than 0, and negative correlations were identified by values less than 0. Statistical significance is indicated when the lower limit of the 95% CI for the correlations. Here, "Number" in measure type is indicating data of Spearman's rank correlation coefficient. Baseline endpoints analysis set included all participants who had baseline measurements and who had at least one dose of study intervention.

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

End point timeframe:

At Baseline (Week 0)

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 40 | | | |
| Units: Correlation coefficient | | | | |
| number (confidence interval 95%) | -0.6892 (-0.8210 to -0.4742) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Correlation between untrimmed total mucus plugs score at TLC and pre-BD FEV1

| End point title | Correlation between untrimmed total mucus plugs score at TLC and pre-BD FEV1 |
|---|---|

End point description:

The relationship between airway dynamics and conventional lung function measurements, cross sectionally (at Week 0) and irrespective of participants characteristics was assessed. Positive correlations were identified by values greater than 0, and negative correlations were identified by values less than 0. Statistical significance is indicated when the lower limit of the 95% CI for the correlations. Here, "Number" in measure type is indicating data of Spearman's rank correlation coefficient. Baseline endpoints analysis set included all participants who had baseline measurements and who had at least one dose of study intervention.

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

End point timeframe:

At Baseline (Week 0)

| End point values | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 43 | | | |
| Units: Correlation coefficient | | | | |
| number (confidence interval 95%) | -0.2795 (-0.5326 to 0.0260) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Correlation between untrimmed total mucus volume measured at TLC and pre-bronchodilator forced expiratory volume in 1 second (pre-BD FEV1)

| End point title | Correlation between untrimmed total mucus volume measured at TLC and pre-bronchodilator forced expiratory volume in 1 second (pre-BD FEV1) |
|---|---|

End point description:

The relationship between airway dynamics and conventional lung function measurements, cross sectionally (at Week 0) and irrespective of participants characteristics was assessed. Positive correlations were identified by values greater than 0, and negative correlations were identified by values less than 0. Statistical significance is indicated when the lower limit of the 95% confidence interval (CI) for the correlations.
Here, "Number" in measure type is indicating data of Spearman's rank correlation coefficient.
Baseline endpoints analysis set included all participants who had baseline measurements and who had at least one dose of study intervention.

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

End point timeframe:

At Baseline (Week 0)

| End point values | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 43 | | | |
| Units: Correlation coefficient | | | | |
| number (confidence interval 95%) | -0.2710 (-0.5260 to 0.0352) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Correlation between trimmed distal airway wall volume at TLC and pre-BD FEV1

| End point title | Correlation between trimmed distal airway wall volume at TLC and pre-BD FEV1 |
|---|---|

End point description:

The relationship between airway dynamics and conventional lung function measurements, cross sectionally (at Week 0) and irrespective of participants characteristics was assessed. Positive correlations were identified by values greater than 0, and negative correlations were identified by values less than 0. Statistical significance is indicated when the lower limit of the 95% CI for the correlations. Here, "Number" in measure type is indicating data of Spearman's rank correlation coefficient. Baseline endpoints analysis set included all participants who had baseline measurements and who had at least one dose of study intervention.

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

End point timeframe:

At Baseline (Week 0)

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 42 | | | |
| Units: Correlation coefficient | | | | |
| number (confidence interval 95%) | 0.5380 (0.2738 to 0.7205) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Correlation between untrimmed total lung volume at TLC and pre-BD FEV1

| End point title | Correlation between untrimmed total lung volume at TLC and pre-BD FEV1 |
|---|---|

End point description:

The relationship between airway dynamics and conventional lung function measurements, cross sectionally (at Week 0) and irrespective of participants characteristics was assessed. Positive correlations were identified by values greater than 0, and negative correlations were identified by values less than 0. Statistical significance is indicated when the lower limit of the 95% CI for the correlations. Here, "Number" in measure type is indicating data of Spearman's rank correlation coefficient. Baseline endpoints analysis set included all participants who had baseline measurements and who had at least one dose of study intervention.

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

End point timeframe:

At Baseline (Week 0)

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 43 | | | |
| Units: Correlation coefficient | | | | |
| number (confidence interval 95%) | 0.2122 (-0.0966 to 0.4799) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Correlation between untrimmed distal airway volume at FRC and pre-BD FEV1

| End point title | Correlation between untrimmed distal airway volume at FRC and pre-BD FEV1 |
|---|---|

End point description:

The relationship between airway dynamics and conventional lung function measurements, cross sectionally (at Week 0) and irrespective of participants characteristics was assessed. Positive correlations were identified by values greater than 0, and negative correlations were identified by values less than 0. Statistical significance is indicated when the lower limit of the 95% CI for the correlations. Here, "Number" in measure type is indicating data of Spearman's rank correlation coefficient. Baseline endpoints analysis set included all participants who had baseline measurements and who had at least one dose of study intervention.

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

End point timeframe:

At Baseline (Week 0)

| End point values | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 43 | | | |
| Units: Correlation coefficient | | | | |
| number (confidence interval 95%) | 0.4357 (0.1383 to 0.6548) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Correlation between untrimmed distal airway volume at TLC and pre-BD FEV1

| End point title | Correlation between untrimmed distal airway volume at TLC and pre-BD FEV1 |
|---|---|

End point description:

The relationship between airway dynamics and conventional lung function measurements, cross sectionally (at Week 0) and irrespective of participants characteristics was assessed. Positive correlations were identified by values greater than 0, and negative correlations were identified by values less than 0. Statistical significance is indicated when the lower limit of the 95% CI for the correlations. Here, "Number" in measure type is indicating data of Spearman's rank correlation coefficient. Baseline endpoints analysis set included all participants who had baseline measurements and who had at least one dose of study intervention.

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

End point timeframe:

At Baseline (Week 0)

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 43 | | | |
| Units: Correlation coefficient | | | | |
| number (confidence interval 95%) | 0.6556 (0.4360 to 0.7958) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Correlation between untrimmed total lung volume at FRC and pre-BD FEV1

| End point title | Correlation between untrimmed total lung volume at FRC and pre-BD FEV1 |
|---|---|

End point description:

The relationship between airway dynamics and conventional lung function measurements, cross sectionally (at Week 0) and irrespective of participants characteristics was assessed. Positive correlations were identified by values greater than 0, and negative correlations were identified by values less than 0. Statistical significance is indicated when the lower limit of the 95% CI for the correlations. Here, "Number" in measure type is indicating data of Spearman's rank correlation coefficient. Baseline endpoints analysis set included all participants who had baseline measurements and who had at least one dose of study intervention.

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

End point timeframe:

At Baseline (Week 0)

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 43 | | | |
| Units: Correlation coefficient | | | | |
| number (confidence interval 95%) | -0.1655 (-0.4519 to 0.1560) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Correlation between untrimmed total mucus plugs score at TLC and pre-BD FVC

| End point title | Correlation between untrimmed total mucus plugs score at TLC and pre-BD FVC |
|---|---|

End point description:

The relationship between airway dynamics and conventional lung function measurements, cross sectionally (at Week 0) and irrespective of participants characteristics was assessed. Positive correlations were identified by values greater than 0, and negative correlations were identified by values less than 0. Statistical significance is indicated when the lower limit of the 95% CI for the correlations. Here, "Number" in measure type is indicating data of Spearman's rank correlation coefficient. Baseline endpoints analysis set included all participants who had baseline measurements and who had at least one dose of study intervention.

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

End point timeframe:

At Baseline (Week 0)

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 43 | | | |
| Units: Correlation coefficient | | | | |
| number (confidence interval 95%) | -0.0273 (-0.3247 to 0.2756) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Correlation between untrimmed total mucus volume measured at TLC and pre-bronchodilator forced vital capacity (pre-BD FVC)

| End point title | Correlation between untrimmed total mucus volume measured at TLC and pre-bronchodilator forced vital capacity (pre-BD FVC) |
|---|---|

End point description:

The relationship between airway dynamics and conventional lung function measurements, cross sectionally (at Week 0) and irrespective of participants characteristics was assessed. Positive correlations were identified by values greater than 0, and negative correlations were identified by values less than 0. Statistical significance is indicated when the lower limit of the 95% CI for the correlations. Here, "Number" in measure type is indicating data of Spearman's rank correlation coefficient. Baseline endpoints analysis set included all participants who had baseline measurements and who had at least one dose of study intervention.

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

End point timeframe:

At Baseline (Week 0)

| End point values | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 43 | | | |
| Units: Correlation coefficient | | | | |
| number (confidence interval 95%) | -0.0471 (-0.3421 to 0.2574) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Correlation between untrimmed total air trapping at FRC and pre-BD FVC

| End point title | Correlation between untrimmed total air trapping at FRC and pre-BD FVC |
|---|---|

End point description:

The relationship between airway dynamics and conventional lung function measurements, cross sectionally (at Week 0) and irrespective of participants characteristics was assessed. Positive correlations were identified by values greater than 0, and negative correlations were identified by values less than 0. Statistical significance is indicated when the lower limit of the 95% CI for the correlations. Here, "Number" in measure type is indicating data of Spearman's rank correlation coefficient. Baseline endpoints analysis set included all participants who had baseline measurements and who had at least one dose of study intervention.

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

End point timeframe:

At Baseline (Week 0)

| End point values | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 40 | | | |
| Units: Correlation coefficient | | | | |
| number (confidence interval 95%) | -0.3432 (-0.5886 to -0.0311) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Correlation between untrimmed distal airway volume at TLC and pre-BD FVC

| End point title | Correlation between untrimmed distal airway volume at TLC and pre-BD FVC |
|---|---|

End point description:

The relationship between airway dynamics and conventional lung function measurements, cross sectionally (at Week 0) and irrespective of participants characteristics was assessed. Positive correlations were identified by values greater than 0, and negative correlations were identified by values less than 0. Statistical significance is indicated when the lower limit of the 95% CI for the correlations.

Here, "Number" in measure type is indicating data of Spearman's rank correlation coefficient.
Baseline endpoints analysis set included all participants who had baseline measurements and who had at least one dose of study intervention.

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

End point timeframe:

At Baseline (Week 0)

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 43 | | | |
| Units: Correlation coefficient | | | | |
| number (confidence interval 95%) | 0.6110 (0.3742 to 0.7670) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Correlation between trimmed distal airway wall volume at TLC and pre-BD FVC

| End point title | Correlation between trimmed distal airway wall volume at TLC and pre-BD FVC |
|---|---|

End point description:

The relationship between airway dynamics and conventional lung function measurements, cross sectionally (at Week 0) and irrespective of participants characteristics was assessed. Positive correlations were identified by values greater than 0, and negative correlations were identified by values less than 0. Statistical significance is indicated when the lower limit of the 95% CI for the correlations.
Here, "Number" in measure type is indicating data of Spearman's rank correlation coefficient.
Baseline endpoints analysis set included all participants who had baseline measurements and who had at least one dose of study intervention.

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

End point timeframe:

At Baseline (Week 0)

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 42 | | | |
| Units: Correlation coefficient | | | | |
| number (confidence interval 95%) | 0.5476 (0.2863 to 0.7269) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Correlation between untrimmed distal airway volume at FRC and pre-BD FVC

| End point title | Correlation between untrimmed distal airway volume at FRC and pre-BD FVC |
|---|---|

End point description:

The relationship between airway dynamics and conventional lung function measurements, cross sectionally (at Week 0) and irrespective of participants characteristics was assessed. Positive correlations were identified by values greater than 0, and negative correlations were identified by values less than 0. Statistical significance is indicated when the lower limit of the 95% CI for the correlations. Here, "Number" in measure type is indicating data of Spearman's rank correlation coefficient. Baseline endpoints analysis set included all participants who had baseline measurements and who had at least one dose of study intervention.

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

End point timeframe:

At Baseline (Week 0)

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 40 | | | |
| Units: Correlation coefficient | | | | |
| number (confidence interval 95%) | 0.4706 (0.1806 to 0.6789) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Correlation between untrimmed total lung volume at TLC and pre-BD FVC

| End point title | Correlation between untrimmed total lung volume at TLC and pre-BD FVC |
|---|---|

End point description:

The relationship between airway dynamics and conventional lung function measurements, cross sectionally (at Week 0) and irrespective of participants characteristics was assessed. Positive correlations were identified by values greater than 0, and negative correlations were identified by values less than 0. Statistical significance is indicated when the lower limit of the 95% CI for the correlations. Here, "Number" in measure type is indicating data of Spearman's rank correlation coefficient. Baseline endpoints analysis set included all participants who had baseline measurements and who had at least one dose of study intervention.

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

End point timeframe:

At Baseline (Week 0)

| End point values | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 43 | | | |
| Units: Correlation coefficient | | | | |
| number (confidence interval 95%) | 0.4947 (0.2227 to 0.6891) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Correlation between untrimmed total lung volume at FRC and pre-BD FVC

| End point title | Correlation between untrimmed total lung volume at FRC and pre-BD FVC |
|---|---|

End point description:

The relationship between airway dynamics and conventional lung function measurements, cross sectionally (at Week 0) and irrespective of participants characteristics was assessed. Positive correlations were identified by values greater than 0, and negative correlations were identified by values less than 0. Statistical significance is indicated when the lower limit of the 95% CI for the correlations. Here, "Number" in measure type is indicating data of Spearman's rank correlation coefficient. Baseline endpoints analysis set included all participants who had baseline measurements and who had at least one dose of study intervention.

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

End point timeframe:

At Baseline (Week 0)

| End point values | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 40 | | | |
| Units: Correlation coefficient | | | | |
| number (confidence interval 95%) | 0.1451 (-0.1761 to 0.4354) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from baseline in untrimmed total mucus volume measured at TLC with and without adjustment for pre-BD FEV1

| End point title | Change from baseline in untrimmed total mucus volume measured at TLC with and without adjustment for pre-BD FEV1 |
|---|---|

End point description:

The relationship between estimated average change from baseline (Week 0) in airway dynamics at Week 13, with and without accounting for baseline measurements of conventional lung function was assessed.

Primary analysis population set consisted portion of the evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during the study period where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13.

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

End point timeframe:

Baseline and Week 13

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 39 | | | |
| Units: mL | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| No adjustment for pre-BD FEV1 (n=39) | 0.05 (0.00 to 0.11) | | | |
| Adjusted for pre-BD FEV1 (n=39) | 0.06 (0.00 to 0.12) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from baseline in untrimmed total mucus plugs score at TLC with and without adjustment for pre-BD FEV1

| End point title | Change from baseline in untrimmed total mucus plugs score at TLC with and without adjustment for pre-BD FEV1 |
|---|---|

End point description:

Relationship between change from baseline (Week 0) in airway dynamics at Week 13, with and without adjustment for pre-BD FEV1 was assessed. Mucus plugs was scored with a scoring system based on BS anatomy. Mucus score was calculated by counting number of BS which contained 1 or more mucus plug, maximum score of 18 related to 18 BS present. Here, a mucus plug is defined as complete occlusion of the airway visible at TLC. Each BS is given a score of 1 (mucus plug present) or 0 (mucus plug absent). The segment scores of each lobe are summed to generate a total mucus score for both lungs, where mucus score ranging from 0-18. Higher scores=worse outcome. Primary analysis population set consisted portion of evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during study period where evaluable population was defined as those who completed three doses of study intervention and had measurements of outcome at both baseline and Week 13.

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

End point timeframe:

Baseline and Week 13

| End point values | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 39 | | | |
| Units: Score on a scale | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| No adjustment for pre-BD FEV1 (n=39) | 4.38 (-2.87 to 11.63) | | | |
| Adjusted for pre-BD FEV1 (n=39) | 5.97 (-1.75 to 13.69) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from baseline in untrimmed total air trapping at FRC with and without adjustment for pre-BD FEV1

| End point title | Change from baseline in untrimmed total air trapping at FRC with and without adjustment for pre-BD FEV1 |
|---|---|

End point description:

The relationship between estimated average change from baseline (Week 0) in airway dynamics at Week 13, with and without accounting for baseline measurements of conventional lung function was assessed. Primary analysis population set consisted portion of the evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during the study period where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13.

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

End point timeframe:

Baseline and Week 13

| End point values | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 34 | | | |
| Units: Percentage of air trapping | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| No adjustment for pre-BD FEV1 (n=34) | 3.18 (-3.65 to 10.01) | | | |
| Adjusted for pre-BD FEV1 (n=34) | 5.24 (-1.23 to 11.71) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from baseline in trimmed distal airway wall volume at TLC with

**and without adjustment for pre-BD FEV1**

| End point title | Change from baseline in trimmed distal airway wall volume at TLC with and without adjustment for pre-BD FEV1 |
|---|---|

End point description:

The relationship between estimated average change from baseline (Week 0) in airway dynamics at Week 13, with and without accounting for baseline measurements of conventional lung function was assessed. Primary analysis population set consisted portion of the evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during the study period where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13.

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

End point timeframe:

Baseline and Week 13

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 39 | | | |
| Units: mL | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| No adjustment for pre-BD FEV1 (n=39) | 5.29 (-1.39 to 11.97) | | | |
| Adjusted for pre-BD FEV1 (n=39) | 5.61 (-1.27 to 12.48) | | | |

## Statistical analyses

No statistical analyses for this end point

**Secondary: Change from baseline in untrimmed distal airway volume with and without adjustment for pre-BD FEV1**

| End point title | Change from baseline in untrimmed distal airway volume with and without adjustment for pre-BD FEV1 |
|---|---|

End point description:

The relationship between estimated average change from baseline (Week 0) in airway dynamics at Week 13, with and without accounting for baseline measurements of conventional lung function was assessed. Primary analysis population set consisted portion of the evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during the study period where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13. Here, 'number analyzed in each row' signifies the participants with available data that were analyzed for specified category.

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

End point timeframe:

Baseline and Week 13

| End point values | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 39 | | | |
| Units: mL | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Distal airway vol. - TLC:No adjust. for pre-BDFEV1 | 2.20 (-1.09 to 5.49) | | | |
| Distal airway vol. at TLC:Adjusted for pre-BD FEV1 | 0.61 (-2.65 to 3.88) | | | |
| Distal airway vol.-FRC:No adjust. for pre-BDFEV1 | -1.28 (-2.82 to 0.27) | | | |
| Distal airway vol. at FRC:Adjusted for pre-BD FEV1 | -1.52 (-3.14 to 0.09) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from baseline in untrimmed total lung volume with and without adjustment for pre-BD FEV1

| End point title | Change from baseline in untrimmed total lung volume with and without adjustment for pre-BD FEV1 |
|---|---|

End point description:

The relationship between estimated average change from baseline (Week 0) in airway dynamics at Week 13, with and without accounting for baseline measurements of conventional lung function was assessed. Primary analysis population set consisted portion of the evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during the study period where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13. Here, 'number analyzed in each row' signifies the participants with available data that were analyzed for specified category.

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

End point timeframe:

Baseline and Week 13

| End point values | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 39 | | | |
| Units: Litre | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Total lung vol. at TLC:No adjust. for pre-BD FEV1 | 0.11 (-0.62 to 0.84) | | | |
| Total lung volume at TLC: Adjusted for pre-BD FEV1 | 0.13 (-0.61 to 0.88) | | | |
| Total lung vol. at FRC:No adjust. for pre-BD FEV1 | 0.52 (-0.16 to 1.21) | | | |
| Total lung volume at FRC: Adjusted for pre-BD FEV1 | 0.37 (-0.25 to 0.99) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from baseline in untrimmed total mucus volume measured at TLC with and without adjustment for pre-BD FVC

| End point title | Change from baseline in untrimmed total mucus volume measured at TLC with and without adjustment for pre-BD FVC |
|---|---|

End point description:

The relationship between estimated average change from baseline (Week 0) in airway dynamics at Week 13, with and without accounting for baseline measurements of conventional lung function was assessed. Primary analysis population set consisted portion of the evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during the study period where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13.

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

End point timeframe:

Baseline and Week 13

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 39 | | | |
| Units: mL | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| No adjustment for pre-BD FVC (n=39) | 0.05 (0.00 to 0.11) | | | |
| Adjusted for pre-BD FVC (n=39) | 0.05 (-0.01 to 0.11) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from baseline in untrimmed total mucus plugs score at TLC with and without adjustment for pre-BD FVC

| End point title | Change from baseline in untrimmed total mucus plugs score at TLC with and without adjustment for pre-BD FVC |
|---|---|

End point description:

Relationship between change from baseline (Week 0) in airway dynamics at Week 13, with and without adjustment for pre-BD FVC was assessed. Mucus plugs was scored with a scoring system based on BS anatomy. Mucus score was calculated by counting the number of BS which contained 1 or more mucus plug, maximum score of 18 related to 18 BS present. Here, a mucus plug is defined as complete

occlusion of the airway visible at TLC. Each BS is given a score of 1 (mucus plug present) or 0 (mucus plug absent). The segment scores of each lobe are summed to generate a total mucus score for both lungs, where mucus score ranging from 0-18. Higher scores=worse outcome. Primary analysis population set consisted portion of evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during study period where evaluable population= those who completed three doses of study intervention and had measurements of outcome at both baseline and Week 13.

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

End point timeframe:

Baseline and Week 13

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 39 | | | |
| Units: Score on a scale | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| No adjustment for pre-BD FVC (n=39) | 4.38 (-2.87 to 11.63) | | | |
| Adjusted for pre-BD FVC (n=39) | 4.65 (-3.00 to 12.30) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change from baseline in untrimmed total air trapping at FRC with and without adjustment for pre-BD FVC

| End point title | Change from baseline in untrimmed total air trapping at FRC with and without adjustment for pre-BD FVC |
|---|---|

End point description:

The relationship between estimated average change from baseline (Week 0) in airway dynamics at Week 13, with and without accounting for baseline measurements of conventional lung function was assessed. Primary analysis population set consisted portion of the evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during the study period where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13.

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

End point timeframe:

Baseline and Week 13

| End point values | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 34 | | | |
| Units: Percentage of air trapping | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| No adjustment for pre-BD FVC (n=34) | 3.18 (-3.65 to 10.01) | | | |
| Adjusted for pre-BD FVC (n=34) | 4.36 (-2.06 to 10.79) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from baseline in trimmed distal airway wall volume at TLC with and without adjustment for pre-BD FVC

| End point title | Change from baseline in trimmed distal airway wall volume at TLC with and without adjustment for pre-BD FVC |
|---|---|

End point description:

The relationship between estimated average change from baseline (Week 0) in airway dynamics at Week 13, with and without accounting for baseline measurements of conventional lung function was assessed. Primary analysis population set consisted portion of the evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during the study period where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13.

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

End point timeframe:

Baseline and Week 13

| End point values | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 39 | | | |
| Units: mL | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| No adjustment for pre-BD FVC (n=39) | 5.29 (-1.39 to 11.97) | | | |
| Adjusted for pre-BD FVC (n=39) | 6.08 (-0.60 to 12.76) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from baseline in untrimmed distal airway volume with and

**without adjustment for pre-BD FVC**

| End point title | Change from baseline in untrimmed distal airway volume with and without adjustment for pre-BD FVC |
|---|---|

End point description:

The relationship between estimated average change from baseline (Week 0) in airway dynamics at Week 13, with and without accounting for baseline measurements of conventional lung function was assessed. Primary analysis population set consisted portion of the evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during the study period where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13. Here, 'number analyzed in each row' signifies the participants with available data that were analyzed for specified category.

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

End point timeframe:

Baseline and Week 13

| **End point values** | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 39 | | | |
| Units: mL | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Distal airway vol. at TLC:No adjust. for pre-BDFVC | 2.20 (-1.09 to 5.49) | | | |
| Distal airway vol. at TLC: Adjusted for pre-BD FVC | 1.22 (-2.30 to 4.73) | | | |
| Distal airway vol. at FRC:No adjust. for pre-BDFVC | -1.28 (-2.82 to 0.27) | | | |
| Distal airway vol. at FRC: Adjusted for pre-BD FVC | -1.28 (-2.93 to 0.37) | | | |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Change from baseline in untrimmed total lung volume with and without adjustment for pre-BD FVC**

| End point title | Change from baseline in untrimmed total lung volume with and without adjustment for pre-BD FVC |
|---|---|

End point description:

The relationship between estimated average change from baseline (Week 0) in airway dynamics at Week 13, with and without accounting for baseline measurements of conventional lung function was assessed. Primary analysis population set consisted portion of the evaluable population that did not have any acute asthma exacerbation nor lower respiratory tract infection during the study period where evaluable population was defined as those who completed the three doses of study intervention and had measurements of the outcome at both baseline and Week 13. Here, 'number analyzed in each row' signifies the participants with available data that were analyzed for specified category.

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

End point timeframe:

Baseline and Week 13

| End point values | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 39 | | | |
| Units: Litre | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Total lung volume at TLC:No adjust. for pre-BD FVC | 0.11 (-0.62 to 0.84) | | | |
| Total lung volume at TLC: Adjusted for pre-BD FVC | 0.11 (-0.63 to 0.85) | | | |
| Total lung volume at FRC:No adjust. for pre-BD FVC | 0.52 (-0.16 to 1.21) | | | |
| Total lung volume at FRC: Adjusted for pre-BD FVC | 0.40 (-0.22 to 1.02) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of participants with adverse events (AEs)

| End point title | Number of participants with adverse events (AEs) |
|---|---|

End point description:

The safety and tolerability of benralizumab was assessed. The Safety analysis set consisted of all participants who had received at least one dose of investigational product.

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

End point timeframe:

From screening (Day -21) to follow-up (up to 1.9 years)

| End point values | Benralizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 45 | | | |
| Units: Participants | | | | |
| Any AE | 17 | | | |
| Any serious adverse event (SAE) | 2 | | | |
| Any SAE with outcome death | 0 | | | |
| Any AE- discontinuation of study intervention | 1 | | | |
| Any possibly related AE | 3 | | | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

| Adverse events information | |
|---|---|
| Timeframe for reporting adverse events: | |
| From screening (Day -21) to follow-up (up to 1.9 years) | |
| Adverse event reporting additional description: | |
| The Safety analysis set consisted of all participants who had received at least one dose of investigational product. | |
| Assessment type | Non-systematic |

| Dictionary used | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 27.0 |

| Reporting groups | |
|---|---|
| Reporting group title | Benralizumab |
| Reporting group description: | |
| Participants received 3 doses of benralizumab 30 mg as subcutaneous injection once every 4 weeks (Week 0, Week 4, and Week 8). | |

| Serious adverse events | Benralizumab | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 45 (4.44%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| **Non-serious adverse events** | Benralizumab | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 3 / 45 (6.67%) | | |
| Infections and infestations | | | |
| Gastroenteritis | | | |
| subjects affected / exposed | 3 / 45 (6.67%) | | |
| occurrences (all) | 4 | | |

## 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