



Clinical trial results:

A Phase 2 single-blind, randomized, controlled, single center study to assess the immunogenicity and safety of a 2-dose schedule with GVGH altSonflex1-2-3 vaccine in African infants (H06_02TP)

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2023-000945-18 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 03 February 2026 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 20 June 2026 |
| First version publication date | 20 June 2026 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 219449 |
|-----------------------|--------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | GlaxoSmithKline |
| Sponsor organisation address | 79 New Oxford Street, London, WC1A 1DG, United Kingdom, TW8 9GS |
| Public contact | GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.com |
| Scientific contact | GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.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? | Yes |

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 17 February 2026 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 03 February 2026 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the immunogenicity profile and the seroresponse of the altSonflex1-2-3 vaccine (low, medium and high dose) administered at 9 and 15 months of age using anti-LPS/OAg enzyme-linked immunosorbent assay (ELISA).

Protection of trial subjects:

Participants were closely monitored for safety including vaccine reactogenicity and any symptoms of anaphylaxis.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 13 November 2024 |
| 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 | Kenya: 200 |
| Worldwide total number of subjects | 200 |
| EEA total number of subjects | 0 |

Notes:

Subjects enrolled per age group

| | |
|---|-----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 200 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

All 200 participants enrolled in the study were included in the Exposed Set.

Period 1

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

Arms

| | |
|------------------------------|--------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | altSonflex1-2-3 Low Dose Group |

Arm description:

Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169.

| | |
|--|--------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | measles and rubella vaccine (MR-VAC) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

2 doses of MR-VAC administered on Day 1 and Day 169.

| | |
|--|--------------------------|
| Investigational medicinal product name | altSonflex1-2-3 low dose |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

2 low doses of altSonflex1-2-3 administered on Day 1 and Day 169.

| | |
|------------------|-----------------------------------|
| Arm title | altSonflex1-2-3 Medium Dose Group |
|------------------|-----------------------------------|

Arm description:

Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169.

| | |
|--|--------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | measles and rubella vaccine (MR-VAC) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

2 doses of MR-VAC administered on Day 1 and Day 169.

| | |
|--|-----------------------------|
| Investigational medicinal product name | altSonflex1-2-3 medium dose |
| Investigational medicinal product code | |
| Other name | |

| | |
|--------------------------|--------------------------|
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

2 medium doses of altSonflex1-2-3 administered on Day 1 and Day 169.

| | |
|------------------|---------------------------------|
| Arm title | altSonflex1-2-3 High Dose Group |
|------------------|---------------------------------|

Arm description:

Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169.

| | |
|--|---------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | altSonflex1-2-3 high dose |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

2 high doses of altSonflex1-2-3 administered on Day 1 and Day 169.

| | |
|--|--------------------------------------|
| Investigational medicinal product name | measles and rubella vaccine (MR-VAC) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

2 doses of MR-VAC administered on Day 1 and Day 169.

| | |
|------------------|---------------|
| Arm title | Control Group |
|------------------|---------------|

Arm description:

Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169.

| | |
|--|--------------------------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | measles and rubella vaccine (MR-VAC) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

2 doses of MR-VAC administered on Day 1 and Day 169.

| | |
|--|-------------------------------------|
| Investigational medicinal product name | Infanrix Hexa |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

1 dose of the Infanrix Hexa vaccine administered on Day 169.

| | |
|--|------------------------|
| Investigational medicinal product name | Typhibev |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

1 dose of the Typhibev vaccine administered on Day 1.

| Number of subjects in period 1 | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group |
|---------------------------------------|--------------------------------|-----------------------------------|---------------------------------|
| Started | 50 | 50 | 50 |
| Completed | 47 | 42 | 48 |
| Not completed | 3 | 8 | 2 |
| Consent withdrawn by subject | 1 | 5 | 2 |
| Not specified | - | 1 | - |
| Lost to follow-up | 2 | 2 | - |

| Number of subjects in period 1 | Control Group |
|---------------------------------------|---------------|
| Started | 50 |
| Completed | 48 |
| Not completed | 2 |
| Consent withdrawn by subject | 2 |
| Not specified | - |
| Lost to follow-up | - |

Baseline characteristics

Reporting groups

| | |
|--|-----------------------------------|
| Reporting group title | altSonflex1-2-3 Low Dose Group |
| Reporting group description: | |
| Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169. | |
| Reporting group title | altSonflex1-2-3 Medium Dose Group |
| Reporting group description: | |
| Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. | |
| Reporting group title | altSonflex1-2-3 High Dose Group |
| Reporting group description: | |
| Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. | |
| Reporting group title | Control Group |
| Reporting group description: | |
| Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. | |

| Reporting group values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group |
|--|--------------------------------|-----------------------------------|---------------------------------|
| Number of subjects | 50 | 50 | 50 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 50 | 50 | 50 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 0 | 0 | 0 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous | | | |
| Units: Months | | | |
| arithmetic mean | 9.3 | 9.3 | 9.3 |
| standard deviation | ± 0.5 | ± 0.5 | ± 0.5 |
| Sex: Female, Male | | | |
| Units: Participants | | | |
| Female | 29 | 21 | 27 |
| Male | 21 | 29 | 23 |
| Race/Ethnicity, Customized | | | |
| Units: Subjects | | | |
| BLACK OR AFRICAN AMERICAN | 50 | 50 | 50 |

| Reporting group values | Control Group | Total | |
|------------------------|---------------|-------|--|
| Number of subjects | 50 | 200 | |

| | | | |
|---|-------|-----|--|
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 50 | 200 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 0 | 0 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Age Continuous | | | |
| Units: Months | | | |
| arithmetic mean | 9.3 | | |
| standard deviation | ± 0.5 | - | |
| Sex: Female, Male | | | |
| Units: Participants | | | |
| Female | 35 | 112 | |
| Male | 15 | 88 | |
| Race/Ethnicity, Customized | | | |
| Units: Subjects | | | |
| BLACK OR AFRICAN AMERICAN | 50 | 200 | |

End points

End points reporting groups

| | |
|--|-----------------------------------|
| Reporting group title | altSonflex1-2-3 Low Dose Group |
| Reporting group description: Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169. | |
| Reporting group title | altSonflex1-2-3 Medium Dose Group |
| Reporting group description: Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. | |
| Reporting group title | altSonflex1-2-3 High Dose Group |
| Reporting group description: Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. | |
| Reporting group title | Control Group |
| Reporting group description: Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. | |

Primary: Geometric mean concentrations (GMCs) of anti-serotype specific Shigella lipopolysaccharide (LPS)/O-Antigen (OAg) serum immunoglobulin G (IgG)

| | |
|---|--|
| End point title | Geometric mean concentrations (GMCs) of anti-serotype specific Shigella lipopolysaccharide (LPS)/O-Antigen (OAg) serum immunoglobulin G (IgG) ^[1] |
| End point description: Anti-serotype specific Shigella LPS/OAg serum IgG GMCs were measured by enzyme-linked immunosorbent assay (ELISA) and expressed in ELISA units per milliliter (EU/mL) of serum. <i>S. sonnei</i> , <i>S. flexneri</i> 1b, <i>S. flexneri</i> 2a, and <i>S. flexneri</i> 3a serotypes were tested. The analysis was performed on the Immunogenicity Set which included all eligible participants who received all doses as per protocol, had immunogenicity results post-dose, complied with dosing/blood draw intervals, without intercurrent conditions that may interfere with immunogenicity and without prohibited concomitant medication/vaccination. Only participants with anti-serotype specific Shigella LPS/OAg serum IgG data available at Day1 were reported in this outcome measure. | |
| End point type | Primary |
| End point timeframe: At Day 1 (before administration of Dose 1) | |

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 analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|--|--------------------------------|-----------------------------------|---------------------------------|-------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 50 | 50 | 50 | 50 |
| Units: EU/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| S. sonnei | 7.4 (6.5 to 8.3) | 8.1 (7.0 to 9.5) | 8.7 (6.6 to 11.5) | 9.2 (7.3 to 11.7) |
| S. flexneri 1b | 5.5 (4.4 to 6.9) | 8.3 (5.7 to 12.1) | 7.6 (5.6 to 10.4) | 6.1 (4.7 to 7.9) |

| | | | | |
|----------------|------------------|------------------|------------------|------------------|
| S. flexneri 2a | 5.1 (3.8 to 6.9) | 4.9 (3.4 to 7.1) | 4.6 (3.1 to 6.8) | 4.0 (2.9 to 5.6) |
| S. flexneri 3a | 3.9 (2.9 to 5.2) | 5.1 (3.4 to 7.6) | 4.2 (3.0 to 6.0) | 4.2 (3.0 to 5.7) |

Statistical analyses

No statistical analyses for this end point

Primary: GMCs of anti-serotype specific Shigella LPS/OAg serum IgG at Day 29

| | |
|------------------------|--|
| End point title | GMCs of anti-serotype specific Shigella LPS/OAg serum IgG at Day 29 ^[2] |
| End point description: | The analysis was performed on the Immunogenicity Set. Only participants with anti-serotype specific Shigella LPS/OAg serum IgG data available at Day 29 were reported in this outcome measure. |
| End point type | Primary |
| End point timeframe: | At Day 29 (28 days after administration of Dose 1) |
| Notes: | |

[2] - 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 analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|--|--------------------------------------|---|---------------------------------------|-------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 48 | 44 | 48 | 48 |
| Units: EU/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| S. sonnei | 44.6 (32.2 to 61.7) | 66.4 (46.9 to 93.9) | 59.5 (44.7 to 79.1) | 8.7 (7.0 to 10.8) |
| S. flexneri 1b | 20.2 (13.9 to 29.5) | 48.7 (35.1 to 67.7) | 30.5 (20.4 to 45.6) | 6.5 (4.8 to 8.9) |
| S. flexneri 2a | 71.3 (43.1 to 117.8) | 98.4 (64.0 to 151.3) | 77.1 (53.8 to 110.5) | 4.5 (3.1 to 6.7) |
| S. flexneri 3a | 11.0 (7.1 to 16.9) | 24.1 (15.4 to 37.9) | 16.6 (11.2 to 24.6) | 5.2 (3.5 to 7.6) |

Statistical analyses

No statistical analyses for this end point

Primary: GMCs of anti-serotype specific Shigella LPS/OAg serum IgG at Day 169

| | |
|------------------------|---|
| End point title | GMCs of anti-serotype specific Shigella LPS/OAg serum IgG at Day 169 ^[3] |
| End point description: | The analysis was performed on the Immunogenicity Set. Only participants with anti-serotype specific Shigella LPS/OAg serum IgG data available at Day 169 were reported in this outcome measure. |
| End point type | Primary |

End point timeframe:

At Day 169 (before administration of Dose 2)

Notes:

[3] - 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 analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|--|--------------------------------------|---|---------------------------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 47 | 44 | 45 | 46 |
| Units: EU/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| S. sonnei | 26.0 (16.4 to 41.3) | 34.7 (22.9 to 52.6) | 33.5 (23.3 to 48.3) | 10.6 (7.1 to 15.8) |
| S. flexneri 1b | 12.0 (8.3 to 17.2) | 16.2 (11.2 to 23.4) | 14.4 (10.0 to 20.9) | 13.2 (9.0 to 19.3) |
| S. flexneri 2a | 11.2 (7.2 to 17.5) | 13.4 (8.8 to 20.6) | 9.6 (6.2 to 14.8) | 6.0 (4.0 to 8.9) |
| S. flexneri 3a | 6.0 (4.0 to 9.0) | 10.1 (6.8 to 14.9) | 8.0 (5.4 to 12.0) | 8.4 (5.5 to 12.7) |

Statistical analyses

No statistical analyses for this end point

Primary: GMCs of anti-serotype specific Shigella LPS/OAg serum IgG at Day 197

| | |
|-----------------|---|
| End point title | GMCs of anti-serotype specific Shigella LPS/OAg serum IgG at Day 197 ^[4] |
|-----------------|---|

End point description:

The analysis was performed on the Immunogenicity Set. Only participants with anti-serotype specific Shigella LPS/OAg serum IgG data available at Day 197 were reported in this outcome measure.

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

End point timeframe:

At Day 197 (28 days after administration of Dose 2)

Notes:

[4] - 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 analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|--|--------------------------------------|---|---------------------------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 44 | 42 | 44 | 45 |
| Units: EU/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| S. sonnei | 802.1 (521.4 to 1234.0) | 1320.3 (903.8 to 1928.8) | 1080.7 (675.7 to 1728.5) | 10.6 (7.2 to 15.6) |

| | | | | |
|----------------|----------------------|----------------------|----------------------|--------------------|
| S. flexneri 1b | 32.0 (23.9 to 42.9) | 39.8 (28.3 to 55.9) | 32.3 (22.5 to 46.3) | 12.4 (8.5 to 18.3) |
| S. flexneri 2a | 83.5 (58.0 to 120.1) | 92.8 (63.7 to 135.1) | 75.3 (52.3 to 108.4) | 5.1 (3.5 to 7.3) |
| S. flexneri 3a | 19.8 (13.4 to 29.2) | 31.9 (23.0 to 44.3) | 19.1 (12.4 to 29.5) | 7.9 (5.1 to 12.1) |

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG at Day 29 compared to Day 1

| | |
|-----------------|--|
| End point title | Number of participants with at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG at Day 29 compared to Day 1 ^[5] |
|-----------------|--|

End point description:

S. sonnei, S. flexneri 1b, S. flexneri 2a, and S. flexneri 3a serotypes were tested. The analysis was performed on the Immunogenicity Set. Only participants with immunogenicity data available for the specified analysis at the specified time points were reported in this outcome measure.

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

End point timeframe:

At Day 29 compared to baseline (before administration of Dose 1 on Day 1)

Notes:

[5] - 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 analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|-----------------------------|--------------------------------------|---|---------------------------------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 48 | 44 | 48 | 48 |
| Units: Participants | | | | |
| S. sonnei | 32 | 31 | 35 | 0 |
| S. flexneri 1b | 21 | 30 | 27 | 3 |
| S. flexneri 2a | 37 | 38 | 39 | 3 |
| S. flexneri 3a | 19 | 23 | 22 | 4 |

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG at Day 197 to Day 1

| | |
|-----------------|--|
| End point title | Number of participants with at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG at Day 197 to Day 1 ^[6] |
|-----------------|--|

End point description:

The analysis was performed on the Immunogenicity Set. Only participants with immunogenicity data

available for the specified analysis at the specified time points were reported in this outcome measure.

| | |
|--|---------|
| End point type | Primary |
| End point timeframe: | |
| At Day 197 compared to baseline (before administration of Dose 1 on Day 1) | |

Notes:

[6] - 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 analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|-----------------------------|--------------------------------------|---|---------------------------------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 44 | 42 | 44 | 45 |
| Units: Participants | | | | |
| S. sonnei | 42 | 42 | 43 | 5 |
| S. flexneri 1b | 28 | 22 | 22 | 11 |
| S. flexneri 2a | 40 | 37 | 37 | 8 |
| S. flexneri 3a | 22 | 24 | 27 | 12 |

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG at Day 197 compared to Day 169

| | |
|-----------------|---|
| End point title | Number of participants with at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG at Day 197 compared to Day 169 ^[7] |
|-----------------|---|

End point description:

The analysis was performed on the Immunogenicity Set. Only participants with immunogenicity data available for the specified analysis at the specified time points were reported in this outcome measure.

| | |
|--|---------|
| End point type | Primary |
| End point timeframe: | |
| At Day 197 compared to pre-Dose 2 at Day 169 | |

Notes:

[7] - 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 analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|-----------------------------|--------------------------------------|---|---------------------------------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 44 | 42 | 44 | 45 |
| Units: Participants | | | | |
| S. sonnei | 36 | 39 | 41 | 0 |
| S. flexneri 1b | 13 | 8 | 8 | 1 |
| S. flexneri 2a | 31 | 30 | 29 | 0 |
| S. flexneri 3a | 16 | 15 | 7 | 3 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with solicited administration site events

| | |
|-----------------|--|
| End point title | Number of participants with solicited administration site events |
|-----------------|--|

End point description:

The solicited administration site events assessed were erythema, pain and swelling. The analysis was performed on the Exposed Set (ES) which included all participants who received at least 1 dose of the study intervention. Only the participants with solicited administration site events data available for the specified time period were reported in this outcome measure.

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

End point timeframe:

During the 7 days after each study intervention administration (study intervention administered at Day 1 and Day 169)

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|--|--------------------------------------|---|---------------------------------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 50 | 50 | 50 | 50 |
| Units: Participants | | | | |
| Erythema, post-Dose 1 (N=50, 50, 50, 50) | 7 | 6 | 6 | 3 |
| Erythema, post-Dose 2 (N=48, 44, 45, 49) | 3 | 3 | 7 | 4 |
| Pain, post-Dose 1 (N=50, 50, 50, 50) | 11 | 14 | 17 | 3 |
| Pain, post-Dose 2 (N=48, 44, 45, 49) | 11 | 13 | 11 | 13 |
| Swelling, post-Dose 1 (N=50, 50, 50, 50) | 7 | 9 | 12 | 2 |
| Swelling, post-Dose 2 (N=48, 44, 45, 49) | 7 | 10 | 7 | 6 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with solicited systemic events

| | |
|-----------------|---|
| End point title | Number of participants with solicited systemic events |
|-----------------|---|

End point description:

The solicited systemic event assessed was fever (pyrexia). Fever is defined as temperature $\geq 38.0^{\circ}\text{C}$ (C), measured axillary. The analysis was performed on the Exposed Set. Only the participants with solicited systemic events data available for the specified time period were reported in this outcome measure.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| During the 7 days after each study intervention administration (study interventions administered at Day 1 and Day 169) | |

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|---------------------------------------|--------------------------------------|---|---------------------------------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 50 | 50 | 50 | 50 |
| Units: Participants | | | | |
| Fever, post-Dose 1 (N=50, 50, 50, 50) | 10 | 6 | 9 | 7 |
| Fever, post-Dose 2 (N=48, 44, 45, 49) | 4 | 10 | 5 | 6 |

Statistical analyses

No statistical analyses for this end point

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

| | |
|---|--|
| End point title | Number of participants with unsolicited adverse events (AEs) |
| End point description: | |
| An unsolicited AE is an AE that was either not included in the list of solicited events or could be included in the list of solicited events but with an onset outside the specified period of follow-up for solicited events. The analysis was performed on the Exposed Set. Only the participants with unsolicited AE data available for the specified time period were reported in this outcome measure. | |
| End point type | Secondary |
| End point timeframe: | |
| During the 28 days after each study intervention administration (study interventions administered at Day 1 and Day 169) | |

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|---|--------------------------------------|---|---------------------------------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 50 | 50 | 50 | 50 |
| Units: Participants | | | | |
| After Day 1 intervention (N=50, 50, 50, 50) | 23 | 23 | 24 | 24 |
| After Day 169 intervention (N=48, 44, 45, 49) | 9 | 14 | 12 | 17 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with change from baseline in hematological, renal, and hepatic panel test results with respect to laboratory reference ranges at Day 8

| | |
|-----------------|---|
| End point title | Number of participants with change from baseline in hematological, renal, and hepatic panel test results with respect to laboratory reference ranges at Day 8 |
|-----------------|---|

End point description:

Panel tests include measures of alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine, potassium, sodium, blood urea, basophils, eosinophils, erythrocytes, hematocrit, hemoglobin, leukocytes, lymphocytes, monocytes, neutrophils and platelets. Categories reported when comparing Day 1 (baseline) and laboratory reference range hematological, renal and hepatic laboratory results are defined as follows: <parameter>,<range at baseline>,<range at timing>, where range is being classified as Below = value below; Within = value within; and Above = value above the laboratory reference range defined for the specified visit and laboratory parameter. The analysis was performed on the Exposed Set. Only the participants with haematological, renal, and hepatic panel test data available at Day 8 were reported in this outcome measure.

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

End point timeframe:

Day 8 compared to baseline (pre-Dose 1 at Day 1)

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|-----------------------------|--------------------------------------|---|---------------------------------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 49 | 46 | 50 | 49 |
| Units: Participants | | | | |
| ALT, Below, Below | 0 | 0 | 1 | 0 |
| ALT, Below, Within | 0 | 0 | 0 | 0 |
| ALT, Below, Above | 0 | 0 | 0 | 0 |
| ALT, Within, Below | 0 | 1 | 0 | 0 |
| ALT, Within, Within | 48 | 43 | 47 | 47 |
| ALT, Within, Above | 1 | 1 | 1 | 1 |
| ALT, Above, Below | 0 | 0 | 0 | 0 |
| ALT, Above, Within | 0 | 1 | 1 | 1 |
| ALT, Above, Above | 0 | 0 | 0 | 0 |
| AST, Below, Below | 0 | 0 | 0 | 0 |
| AST, Below, Within | 0 | 0 | 0 | 0 |
| AST, Below, Above | 0 | 0 | 0 | 0 |
| AST, Within, Below | 0 | 0 | 0 | 0 |
| AST, Within, Within | 48 | 45 | 50 | 48 |
| AST, Within, Above | 0 | 0 | 0 | 1 |
| AST, Above, Below | 0 | 0 | 0 | 0 |
| AST, Above, Within | 0 | 1 | 0 | 0 |
| AST, Above, Above | 1 | 0 | 0 | 0 |
| Creatinine, Below, Below | 49 | 46 | 50 | 49 |
| Creatinine, Below, Within | 0 | 0 | 0 | 0 |
| Creatinine, Below, Above | 0 | 0 | 0 | 0 |
| Creatinine, Within, Below | 0 | 0 | 0 | 0 |
| Creatinine, Within, Within | 0 | 0 | 0 | 0 |
| Creatinine, Within, Above | 0 | 0 | 0 | 0 |
| Creatinine, Above, Below | 0 | 0 | 0 | 0 |
| Creatinine, Above, Within | 0 | 0 | 0 | 0 |

| | | | | |
|------------------------------|----|----|----|----|
| Creatinine, Above, Above | 0 | 0 | 0 | 0 |
| Potassium, Below, Below | 0 | 0 | 0 | 0 |
| Potassium, Below, Within | 0 | 0 | 0 | 0 |
| Potassium, Below, Above | 0 | 0 | 0 | 0 |
| Potassium, Within, Below | 1 | 0 | 0 | 0 |
| Potassium, Within, Within | 48 | 46 | 50 | 49 |
| Potassium, Within, Above | 0 | 0 | 0 | 0 |
| Potassium, Above, Below | 0 | 0 | 0 | 0 |
| Potassium, Above, Within | 0 | 0 | 0 | 0 |
| Potassium, Above, Above | 0 | 0 | 0 | 0 |
| Sodium, Below, Below | 0 | 0 | 0 | 0 |
| Sodium, Below, Within | 1 | 1 | 0 | 0 |
| Sodium, Below, Above | 0 | 0 | 0 | 0 |
| Sodium, Within, Below | 0 | 1 | 0 | 0 |
| Sodium, Within, Within | 31 | 35 | 37 | 35 |
| Sodium, Within, Above | 10 | 6 | 7 | 6 |
| Sodium, Above, Below | 0 | 0 | 0 | 0 |
| Sodium, Above, Within | 4 | 3 | 6 | 5 |
| Sodium, Above, Above | 3 | 0 | 0 | 3 |
| Urea, Below, Below | 23 | 29 | 20 | 24 |
| Urea, Below, Within | 11 | 1 | 7 | 7 |
| Urea, Below, Above | 0 | 0 | 0 | 0 |
| Urea, Within, Below | 6 | 6 | 10 | 10 |
| Urea, Within, Within | 9 | 9 | 13 | 8 |
| Urea, Within, Above | 0 | 1 | 0 | 0 |
| Urea, Above, Below | 0 | 0 | 0 | 0 |
| Urea, Above, Within | 0 | 0 | 0 | 0 |
| Urea, Above, Above | 0 | 0 | 0 | 0 |
| Basophils, Below, Below | 0 | 0 | 0 | 0 |
| Basophils, Below, Within | 0 | 0 | 0 | 0 |
| Basophils, Below, Above | 0 | 0 | 0 | 0 |
| Basophils, Within, Below | 0 | 0 | 0 | 0 |
| Basophils, Within, Within | 27 | 28 | 33 | 32 |
| Basophils, Within, Above | 3 | 6 | 4 | 4 |
| Basophils, Above, Below | 0 | 0 | 0 | 0 |
| Basophils, Above, Within | 11 | 8 | 9 | 8 |
| Basophils, Above, Above | 8 | 4 | 4 | 5 |
| Eosinophils, Below, Below | 0 | 0 | 0 | 0 |
| Eosinophils, Below, Within | 1 | 0 | 1 | 0 |
| Eosinophils, Below, Above | 0 | 0 | 0 | 0 |
| Eosinophils, Within, Below | 2 | 3 | 0 | 0 |
| Eosinophils, Within, Within | 40 | 40 | 48 | 45 |
| Eosinophils, Within, Above | 2 | 1 | 0 | 2 |
| Eosinophils, Above, Below | 0 | 0 | 0 | 0 |
| Eosinophils, Above, Within | 3 | 0 | 0 | 1 |
| Eosinophils, Above, Above | 1 | 2 | 1 | 1 |
| Erythrocytes, Below, Below | 0 | 0 | 0 | 0 |
| Erythrocytes, Below, Within | 0 | 0 | 0 | 0 |
| Erythrocytes, Below, Above | 0 | 0 | 0 | 0 |
| Erythrocytes, Within, Below | 1 | 1 | 0 | 1 |
| Erythrocytes, Within, Within | 25 | 28 | 28 | 29 |
| Erythrocytes, Within, Above | 7 | 3 | 4 | 3 |

| | | | | |
|-----------------------------|----|----|----|----|
| Erythrocytes, Above, Below | 0 | 0 | 0 | 0 |
| Erythrocytes, Above, Within | 1 | 6 | 6 | 4 |
| Erythrocytes, Above, Above | 15 | 8 | 12 | 12 |
| Hematocrit, Below, Below | 0 | 0 | 1 | 1 |
| Hematocrit, Below, Within | 2 | 3 | 0 | 3 |
| Hematocrit, Below, Above | 0 | 0 | 0 | 0 |
| Hematocrit, Within, Below | 1 | 3 | 0 | 0 |
| Hematocrit, Within, Within | 38 | 36 | 38 | 34 |
| Hematocrit, Within, Above | 6 | 0 | 5 | 4 |
| Hematocrit, Above, Below | 0 | 0 | 0 | 0 |
| Hematocrit, Above, Within | 1 | 1 | 3 | 4 |
| Hematocrit, Above, Above | 1 | 3 | 3 | 3 |
| Hemoglobin, Below, Below | 5 | 3 | 4 | 2 |
| Hemoglobin, Below, Within | 1 | 3 | 2 | 4 |
| Hemoglobin, Below, Above | 0 | 0 | 0 | 0 |
| Hemoglobin, Within, Below | 1 | 4 | 1 | 1 |
| Hemoglobin, Within, Within | 40 | 32 | 37 | 38 |
| Hemoglobin, Within, Above | 1 | 1 | 2 | 2 |
| Hemoglobin, Above, Below | 0 | 0 | 0 | 0 |
| Hemoglobin, Above, Within | 1 | 2 | 2 | 2 |
| Hemoglobin, Above, Above | 0 | 1 | 2 | 0 |
| Leukocytes, Below, Below | 0 | 0 | 3 | 1 |
| Leukocytes, Below, Within | 1 | 2 | 3 | 2 |
| Leukocytes, Below, Above | 0 | 0 | 0 | 0 |
| Leukocytes, Within, Below | 4 | 1 | 1 | 2 |
| Leukocytes, Within, Within | 31 | 30 | 31 | 33 |
| Leukocytes, Within, Above | 3 | 4 | 4 | 1 |
| Leukocytes, Above, Below | 0 | 0 | 0 | 0 |
| Leukocytes, Above, Within | 5 | 9 | 4 | 7 |
| Leukocytes, Above, Above | 5 | 0 | 4 | 3 |
| Lymphocytes, Below, Below | 0 | 0 | 0 | 0 |
| Lymphocytes, Below, Within | 0 | 0 | 0 | 0 |
| Lymphocytes, Below, Above | 0 | 0 | 0 | 0 |
| Lymphocytes, Within, Below | 0 | 0 | 0 | 0 |
| Lymphocytes, Within, Within | 30 | 30 | 26 | 33 |
| Lymphocytes, Within, Above | 5 | 3 | 8 | 5 |
| Lymphocytes, Above, Below | 0 | 0 | 0 | 0 |
| Lymphocytes, Above, Within | 6 | 6 | 7 | 6 |
| Lymphocytes, Above, Above | 8 | 7 | 9 | 5 |
| Monocytes, Below, Below | 0 | 1 | 0 | 0 |
| Monocytes, Below, Within | 2 | 3 | 0 | 4 |
| Monocytes, Below, Above | 0 | 0 | 0 | 0 |
| Monocytes, Within, Below | 1 | 0 | 1 | 1 |
| Monocytes, Within, Within | 27 | 29 | 39 | 27 |
| Monocytes, Within, Above | 12 | 8 | 6 | 11 |
| Monocytes, Above, Below | 0 | 0 | 0 | 0 |
| Monocytes, Above, Within | 2 | 2 | 3 | 4 |
| Monocytes, Above, Above | 5 | 3 | 1 | 2 |
| Neutrophils, Below, Below | 3 | 3 | 2 | 7 |
| Neutrophils, Below, Within | 4 | 6 | 2 | 3 |
| Neutrophils, Below, Above | 0 | 0 | 0 | 0 |
| Neutrophils, Within, Below | 10 | 1 | 8 | 6 |

| | | | | |
|-----------------------------|----|----|----|----|
| Neutrophils, Within, Within | 31 | 33 | 35 | 33 |
| Neutrophils, Within, Above | 1 | 1 | 1 | 0 |
| Neutrophils, Above, Below | 0 | 0 | 0 | 0 |
| Neutrophils, Above, Within | 0 | 2 | 2 | 0 |
| Neutrophils, Above, Above | 0 | 0 | 0 | 0 |
| Platelets, Below, Below | 0 | 0 | 0 | 0 |
| Platelets, Below, Within | 0 | 0 | 1 | 0 |
| Platelets, Below, Above | 0 | 0 | 0 | 0 |
| Platelets, Within, Below | 0 | 0 | 0 | 0 |
| Platelets, Within, Within | 7 | 5 | 10 | 24 |
| Platelets, Within, Above | 9 | 7 | 8 | 3 |
| Platelets, Above, Below | 0 | 0 | 0 | 0 |
| Platelets, Above, Within | 8 | 10 | 2 | 11 |
| Platelets, Above, Above | 25 | 24 | 29 | 11 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with serious AEs (SAEs)

| | |
|--|--|
| End point title | Number of participants with serious AEs (SAEs) |
| End point description: | |
| An SAE is defined as any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect in the offspring of a study participant, results in abnormal pregnancy outcomes or any other situation based on appropriate medical or scientific judgement. The analysis was performed on the Exposed Set. Only the participants with SAE data available for the specified time period were reported in this outcome measure. | |
| End point type | Secondary |
| End point timeframe: | |
| Day 1 to Day 197 | |

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|-----------------------------|--------------------------------------|---|---------------------------------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 50 | 50 | 50 | 50 |
| Units: Participants | 1 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with change from baseline in hematological, renal, and hepatic panel test results with respect to laboratory reference ranges at Day 176

| | |
|--|---|
| End point title | Number of participants with change from baseline in hematological, renal, and hepatic panel test results with respect to laboratory reference ranges at Day 176 |
| End point description: | |
| Panel tests include measures of alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine, potassium, sodium, blood urea, basophils, eosinophils, erythrocytes, hematocrit, hemoglobin, leukocytes, lymphocytes, monocytes, neutrophils and platelets. Categories reported when comparing Day 169 (baseline) and laboratory reference range hematological, renal and hepatic laboratory results are defined as follows: <parameter>,<range at baseline>,<range at timing>, where range is being classified as Below = value below; Within = value within; and Above = value above the laboratory reference range defined for the specified visit and laboratory parameter. The analysis was performed on the Exposed Set. Only the participants with haematological, renal, and hepatic panel test data available at Day 176 were reported in this outcome measure. | |
| End point type | Secondary |
| End point timeframe: | |
| Day 176 compared to pre-Dose 2 at Day 169 | |

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|-----------------------------|--------------------------------------|---|---------------------------------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 46 | 43 | 46 | 49 |
| Units: Participants | | | | |
| ALT, Below, Below | 0 | 1 | 1 | 0 |
| ALT, Below, Within | 0 | 0 | 0 | 0 |
| ALT, Below, Above | 0 | 0 | 0 | 0 |
| ALT, Within, Below | 0 | 0 | 0 | 0 |
| ALT, Within, Within | 44 | 42 | 44 | 46 |
| ALT, Within, Above | 1 | 0 | 0 | 1 |
| ALT, Above, Below | 0 | 0 | 0 | 0 |
| ALT, Above, Within | 0 | 0 | 0 | 1 |
| ALT, Above, Above | 1 | 0 | 1 | 1 |
| AST, Below, Below | 0 | 0 | 0 | 0 |
| AST, Below, Within | 0 | 0 | 0 | 0 |
| AST, Below, Above | 0 | 0 | 0 | 0 |
| AST, Within, Below | 0 | 0 | 0 | 0 |
| AST, Within, Within | 43 | 41 | 45 | 47 |
| AST, Within, Above | 0 | 0 | 0 | 1 |
| AST, Above, Below | 0 | 0 | 0 | 0 |
| AST, Above, Within | 1 | 2 | 0 | 0 |
| AST, Above, Above | 2 | 0 | 1 | 1 |
| Creatinine, Below, Below | 45 | 43 | 45 | 47 |
| Creatinine, Below, Within | 0 | 0 | 1 | 1 |
| Creatinine, Below, Above | 1 | 0 | 0 | 0 |
| Creatinine, Within, Below | 0 | 0 | 0 | 1 |
| Creatinine, Within, Within | 0 | 0 | 0 | 0 |
| Creatinine, Within, Above | 0 | 0 | 0 | 0 |
| Creatinine, Above, Below | 0 | 0 | 0 | 0 |
| Creatinine, Above, Within | 0 | 0 | 0 | 0 |
| Creatinine, Above, Above | 0 | 0 | 0 | 0 |
| Potassium, Below, Below | 0 | 0 | 0 | 0 |
| Potassium, Below, Within | 0 | 0 | 0 | 0 |

| | | | | |
|------------------------------|----|----|----|----|
| Potassium, Below, Above | 0 | 0 | 0 | 0 |
| Potassium, Within, Below | 0 | 0 | 0 | 0 |
| Potassium, Within, Within | 11 | 11 | 6 | 17 |
| Potassium, Within, Above | 9 | 10 | 14 | 13 |
| Potassium, Above, Below | 0 | 0 | 0 | 0 |
| Potassium, Above, Within | 9 | 6 | 6 | 2 |
| Potassium, Above, Above | 17 | 16 | 20 | 17 |
| Sodium, Below, Below | 0 | 0 | 0 | 0 |
| Sodium, Below, Within | 0 | 0 | 0 | 0 |
| Sodium, Below, Above | 0 | 0 | 0 | 0 |
| Sodium, Within, Below | 0 | 0 | 0 | 0 |
| Sodium, Within, Within | 37 | 38 | 40 | 39 |
| Sodium, Within, Above | 6 | 3 | 2 | 2 |
| Sodium, Above, Below | 0 | 0 | 0 | 0 |
| Sodium, Above, Within | 3 | 2 | 4 | 8 |
| Sodium, Above, Above | 0 | 0 | 0 | 0 |
| Urea, Below, Below | 17 | 17 | 16 | 19 |
| Urea, Below, Within | 11 | 4 | 9 | 11 |
| Urea, Below, Above | 0 | 0 | 0 | 0 |
| Urea, Within, Below | 7 | 4 | 6 | 10 |
| Urea, Within, Within | 11 | 18 | 15 | 9 |
| Urea, Within, Above | 0 | 0 | 0 | 0 |
| Urea, Above, Below | 0 | 0 | 0 | 0 |
| Urea, Above, Within | 0 | 0 | 0 | 0 |
| Urea, Above, Above | 0 | 0 | 0 | 0 |
| Basophils, Below, Below | 0 | 0 | 0 | 0 |
| Basophils, Below, Within | 0 | 0 | 0 | 0 |
| Basophils, Below, Above | 0 | 0 | 0 | 0 |
| Basophils, Within, Below | 1 | 0 | 0 | 0 |
| Basophils, Within, Within | 39 | 37 | 43 | 45 |
| Basophils, Within, Above | 2 | 2 | 1 | 2 |
| Basophils, Above, Below | 0 | 0 | 0 | 0 |
| Basophils, Above, Within | 1 | 2 | 2 | 1 |
| Basophils, Above, Above | 3 | 2 | 0 | 1 |
| Eosinophils, Below, Below | 0 | 0 | 0 | 0 |
| Eosinophils, Below, Within | 0 | 1 | 0 | 1 |
| Eosinophils, Below, Above | 0 | 0 | 0 | 0 |
| Eosinophils, Within, Below | 0 | 2 | 0 | 0 |
| Eosinophils, Within, Within | 38 | 29 | 40 | 39 |
| Eosinophils, Within, Above | 2 | 2 | 4 | 2 |
| Eosinophils, Above, Below | 0 | 0 | 0 | 0 |
| Eosinophils, Above, Within | 2 | 0 | 1 | 5 |
| Eosinophils, Above, Above | 4 | 9 | 1 | 2 |
| Erythrocytes, Below, Below | 0 | 0 | 0 | 0 |
| Erythrocytes, Below, Within | 0 | 0 | 0 | 0 |
| Erythrocytes, Below, Above | 0 | 0 | 0 | 0 |
| Erythrocytes, Within, Below | 0 | 0 | 0 | 0 |
| Erythrocytes, Within, Within | 29 | 31 | 28 | 28 |
| Erythrocytes, Within, Above | 2 | 3 | 3 | 2 |
| Erythrocytes, Above, Below | 0 | 0 | 0 | 0 |
| Erythrocytes, Above, Within | 3 | 3 | 5 | 6 |
| Erythrocytes, Above, Above | 12 | 6 | 10 | 13 |

| | | | | |
|-----------------------------|----|----|----|----|
| Hematocrit, Below, Below | 0 | 0 | 1 | 1 |
| Hematocrit, Below, Within | 0 | 1 | 2 | 1 |
| Hematocrit, Below, Above | 0 | 0 | 0 | 0 |
| Hematocrit, Within, Below | 1 | 1 | 1 | 1 |
| Hematocrit, Within, Within | 32 | 36 | 33 | 33 |
| Hematocrit, Within, Above | 4 | 2 | 3 | 3 |
| Hematocrit, Above, Below | 0 | 0 | 0 | 0 |
| Hematocrit, Above, Within | 2 | 1 | 4 | 6 |
| Hematocrit, Above, Above | 7 | 2 | 2 | 4 |
| Hemoglobin, Below, Below | 2 | 6 | 4 | 6 |
| Hemoglobin, Below, Within | 1 | 1 | 2 | 1 |
| Hemoglobin, Below, Above | 0 | 0 | 0 | 0 |
| Hemoglobin, Within, Below | 0 | 1 | 1 | 1 |
| Hemoglobin, Within, Within | 35 | 31 | 38 | 35 |
| Hemoglobin, Within, Above | 2 | 1 | 1 | 2 |
| Hemoglobin, Above, Below | 0 | 0 | 0 | 0 |
| Hemoglobin, Above, Within | 4 | 2 | 0 | 1 |
| Hemoglobin, Above, Above | 2 | 1 | 0 | 3 |
| Leukocytes, Below, Below | 0 | 1 | 0 | 1 |
| Leukocytes, Below, Within | 1 | 2 | 4 | 2 |
| Leukocytes, Below, Above | 0 | 0 | 0 | 0 |
| Leukocytes, Within, Below | 1 | 0 | 0 | 0 |
| Leukocytes, Within, Within | 30 | 32 | 28 | 40 |
| Leukocytes, Within, Above | 4 | 3 | 6 | 3 |
| Leukocytes, Above, Below | 0 | 0 | 0 | 0 |
| Leukocytes, Above, Within | 5 | 2 | 3 | 1 |
| Leukocytes, Above, Above | 5 | 3 | 5 | 2 |
| Lymphocytes, Below, Below | 0 | 0 | 0 | 0 |
| Lymphocytes, Below, Within | 0 | 0 | 0 | 0 |
| Lymphocytes, Below, Above | 0 | 0 | 0 | 0 |
| Lymphocytes, Within, Below | 0 | 0 | 0 | 0 |
| Lymphocytes, Within, Within | 28 | 33 | 25 | 35 |
| Lymphocytes, Within, Above | 7 | 3 | 7 | 9 |
| Lymphocytes, Above, Below | 0 | 0 | 0 | 0 |
| Lymphocytes, Above, Within | 2 | 2 | 4 | 2 |
| Lymphocytes, Above, Above | 9 | 5 | 10 | 3 |
| Monocytes, Below, Below | 0 | 0 | 0 | 0 |
| Monocytes, Below, Within | 0 | 0 | 0 | 0 |
| Monocytes, Below, Above | 0 | 0 | 0 | 0 |
| Monocytes, Within, Below | 0 | 0 | 0 | 0 |
| Monocytes, Within, Within | 36 | 36 | 38 | 42 |
| Monocytes, Within, Above | 3 | 3 | 3 | 5 |
| Monocytes, Above, Below | 0 | 0 | 0 | 0 |
| Monocytes, Above, Within | 7 | 1 | 4 | 2 |
| Monocytes, Above, Above | 0 | 3 | 1 | 0 |
| Neutrophils, Below, Below | 2 | 2 | 3 | 0 |
| Neutrophils, Below, Within | 4 | 3 | 0 | 7 |
| Neutrophils, Below, Above | 0 | 0 | 0 | 0 |
| Neutrophils, Within, Below | 2 | 6 | 2 | 2 |
| Neutrophils, Within, Within | 35 | 32 | 40 | 38 |
| Neutrophils, Within, Above | 0 | 0 | 0 | 1 |
| Neutrophils, Above, Below | 0 | 0 | 0 | 0 |

| | | | | |
|----------------------------|----|----|----|----|
| Neutrophils, Above, Within | 3 | 0 | 1 | 1 |
| Neutrophils, Above, Above | 0 | 0 | 0 | 0 |
| Platelets, Below, Below | 0 | 0 | 0 | 0 |
| Platelets, Below, Within | 0 | 0 | 0 | 0 |
| Platelets, Below, Above | 1 | 1 | 1 | 0 |
| Platelets, Within, Below | 0 | 0 | 0 | 0 |
| Platelets, Within, Within | 7 | 5 | 6 | 20 |
| Platelets, Within, Above | 10 | 6 | 12 | 12 |
| Platelets, Above, Below | 0 | 0 | 0 | 0 |
| Platelets, Above, Within | 3 | 4 | 3 | 3 |
| Platelets, Above, Above | 25 | 27 | 24 | 14 |

Statistical analyses

No statistical analyses for this end point

Secondary: The number of participants with abnormal hematological, renal, and hepatic panel test results by Grade values at Day 8 versus baseline (Day 1) Grade values

| | |
|-----------------|---|
| End point title | The number of participants with abnormal hematological, renal, and hepatic panel test results by Grade values at Day 8 versus baseline (Day 1) Grade values |
|-----------------|---|

End point description:

Panel tests include measures of ALT, AST, creatinine, hemoglobin, neutrophils decrease, platelets decrease and white blood cells (WBC) decrease. Categories reported when comparing Day 1 (baseline) and laboratory reference range hematological, renal and hepatic laboratory results are defined as follows: <parameter>, <grade at baseline>, <grade at timing>, where Grade 0=within reference range, Grade 1= mild, Grade 2=moderate, Grade 3=severe and Grade 4=potentially life threatening laboratory abnormality. The analysis was performed on the Exposed Set. Only the participants with haematological, renal, and hepatic panel test data available at Day 8 were reported in this outcome measure.

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

End point timeframe:

Day 8 compared to baseline (before administration of Dose 1 at Day 1)

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|--|--------------------------------------|---|---------------------------------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 49 | 46 | 50 | 49 |
| Units: Participants | | | | |
| ALT, Grade 0, Grade 0 | 49 | 45 | 50 | 48 |
| ALT, Grade 0, Grade 1 | 0 | 1 | 0 | 1 |
| AST, Grade 0, Grade 0 | 49 | 46 | 50 | 49 |
| Creatinine, Grade 0, Grade 0 | 49 | 46 | 50 | 49 |
| Hemoglobin, Grade 0, Grade 0 | 42 | 36 | 43 | 42 |
| Hemoglobin, Grade 0, Grade 1 | 1 | 4 | 1 | 1 |
| Hemoglobin, Grade 1, Grade 0 | 1 | 3 | 2 | 4 |
| Hemoglobin, Grade 1, Grade 1 | 5 | 2 | 4 | 2 |
| Hemoglobin, Grade 2, Grade 2 | 0 | 1 | 0 | 0 |
| Neutrophils Decrease, Grade 0, Grade 0 | 32 | 36 | 38 | 33 |

| | | | | |
|--|----|----|----|----|
| Neutrophils Decrease, Grade 0, Grade 1 | 8 | 1 | 8 | 6 |
| Neutrophils Decrease, Grade 1, Grade 0 | 1 | 5 | 2 | 2 |
| Neutrophils Decrease, Grade 1, Grade 1 | 1 | 2 | 1 | 5 |
| Neutrophils Decrease, Grade 1, Grade 2 | 0 | 0 | 0 | 1 |
| Neutrophils Decrease, Grade 1, Grade 3 | 0 | 1 | 0 | 1 |
| Neutrophils Decrease, Grade 1, Grade 4 | 1 | 0 | 0 | 0 |
| Neutrophils Decrease, Grade 2, Grade 0 | 2 | 0 | 0 | 1 |
| Neutrophils Decrease, Grade 2, Grade 1 | 1 | 0 | 0 | 0 |
| Neutrophils Decrease, Grade 3, Grade 0 | 1 | 1 | 0 | 0 |
| Neutrophils Decrease, Grade 3, Grade 1 | 0 | 0 | 1 | 0 |
| Platelets Decrease, Grade 0, Grade 0 | 49 | 46 | 49 | 49 |
| Platelets Decrease, Grade 1, Grade 0 | 0 | 0 | 1 | 0 |
| WBC Decrease, Grade 0, Grade 0 | 44 | 43 | 43 | 44 |
| WBC Decrease, Grade 0, Grade 1 | 4 | 1 | 1 | 2 |
| WBC Decrease, Grade 1, Grade 0 | 1 | 2 | 3 | 2 |
| WBC Decrease, Grade 1, Grade 1 | 0 | 0 | 3 | 1 |

Statistical analyses

No statistical analyses for this end point

Secondary: The number of participants with abnormal hematological, renal, and hepatic panel test results by Grade values at Day 176 versus Day 169 Grade values

| | |
|-----------------|--|
| End point title | The number of participants with abnormal hematological, renal, and hepatic panel test results by Grade values at Day 176 versus Day 169 Grade values |
|-----------------|--|

End point description:

Panel tests include measures of ALT, AST, creatinine, hemoglobin, neutrophils decrease, platelets decrease and white blood cells (WBC) decrease. Categories reported when comparing Day 169 and laboratory reference range hematological, renal and hepatic laboratory results are defined as follows: <parameter>,<grade at baseline>,<grade at timing>, where Grade 0=within reference range, Grade 1= mild, Grade 2=moderate, Grade 3=severe and Grade 4=potentially life threatening laboratory abnormality. The analysis was performed on the Exposed Set. Only the participants with haematological, renal, and hepatic panel test data available at Day 176 were reported in this outcome measure.

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

End point timeframe:

Day 176 compared to pre-Dose 2 at Day 169

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|-----------------------------|--------------------------------------|---|---------------------------------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 46 | 43 | 46 | 49 |
| Units: Participants | | | | |
| ALT, Grade 0, Grade 0 | 45 | 43 | 45 | 48 |
| ALT, Grade 0, Grade 1 | 0 | 0 | 0 | 1 |
| ALT, Grade 1, Grade 0 | 1 | 0 | 0 | 0 |
| ALT, Grade 1, Grade 2 | 0 | 0 | 1 | 0 |
| AST, Grade 0, Grade 0 | 45 | 43 | 45 | 48 |

| | | | | |
|--|----|----|----|----|
| AST, Grade 1, Grade 0 | 1 | 0 | 0 | 1 |
| AST, Grade 1, Grade 1 | 0 | 0 | 1 | 0 |
| Creatinine, Grade 0, Grade 0 | 45 | 43 | 46 | 48 |
| Creatinine, Grade 0, Grade 2 | 1 | 0 | 0 | 1 |
| Hemoglobin, Grade 0, Grade 0 | 43 | 35 | 39 | 41 |
| Hemoglobin, Grade 0, Grade 1 | 0 | 1 | 1 | 1 |
| Hemoglobin, Grade 1, Grade 0 | 1 | 1 | 2 | 1 |
| Hemoglobin, Grade 1, Grade 1 | 1 | 3 | 0 | 2 |
| Hemoglobin, Grade 1, Grade 2 | 0 | 1 | 2 | 3 |
| Hemoglobin, Grade 2, Grade 1 | 0 | 2 | 2 | 0 |
| Hemoglobin, Grade 2, Grade 2 | 1 | 0 | 0 | 0 |
| Hemoglobin, Grade 2, Grade 3 | 0 | 0 | 0 | 1 |
| Neutrophils Decrease, Grade 0, Grade 0 | 38 | 32 | 41 | 41 |
| Neutrophils Decrease, Grade 0, Grade 1 | 2 | 6 | 2 | 1 |
| Neutrophils Decrease, Grade 1, Grade 0 | 2 | 2 | 0 | 7 |
| Neutrophils Decrease, Grade 1, Grade 1 | 2 | 0 | 3 | 0 |
| Neutrophils Decrease, Grade 1, Grade 2 | 0 | 0 | 0 | 0 |
| Neutrophils Decrease, Grade 1, Grade 3 | 0 | 0 | 0 | 0 |
| Neutrophils Decrease, Grade 1, Grade 4 | 0 | 0 | 0 | 0 |
| Neutrophils Decrease, Grade 2, Grade 0 | 2 | 0 | 0 | 0 |
| Neutrophils Decrease, Grade 2, Grade 1 | 0 | 0 | 0 | 0 |
| Neutrophils Decrease, Grade 2, Grade 2 | 0 | 1 | 0 | 0 |
| Neutrophils Decrease, Grade 3, Grade 0 | 0 | 1 | 0 | 0 |
| Neutrophils Decrease, Grade 3, Grade 1 | 0 | 1 | 0 | 0 |
| Platelets Decrease, Grade 0, Grade 0 | 45 | 42 | 45 | 49 |
| Platelets Decrease, Grade 1, Grade 0 | 1 | 1 | 1 | 0 |
| WBC Decrease, Grade 0, Grade 0 | 44 | 40 | 42 | 46 |
| WBC Decrease, Grade 0, Grade 1 | 1 | 0 | 0 | 0 |
| WBC Decrease, Grade 1, Grade 0 | 1 | 2 | 4 | 2 |
| WBC Decrease, Grade 1, Grade 1 | 0 | 1 | 0 | 1 |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-measles IgG concentrations expressed as GMCs

| | |
|-----------------|---|
| End point title | Anti-measles IgG concentrations expressed as GMCs |
|-----------------|---|

End point description:

Anti-measles IgG concentrations were expressed as GMCs in EU/mL. The analysis was performed on the Immunogenicity Set. Only the participants with anti-measles IgG concentrations data available at the specified timepoints were reported in this outcome measure.

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

End point timeframe:

At Day 1 (before the first MR-VAC) and at Day 197 (28 days after the second MR-VAC vaccination)

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|--|--------------------------------------|---|---------------------------------------|-------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 50 | 50 | 50 | 50 |
| Units: EU/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Day 1 (N= 50, 50, 50, 50) | 25.4 (24.6 to 26.2) | 25.0 (25.0 to 25.0) | 25.5 (24.5 to 26.4) | 25.8 (24.2 to 27.5) |
| Day 197 (N=44, 42, 44, 45) | 1005.0 (855.0 to 1181.3) | 835.6 (685.7 to 1018.3) | 923.9 (783.7 to 1089.0) | 954.1 (836.2 to 1088.6) |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-rubella IgG concentrations expressed as GMCs

| | |
|-----------------|---|
| End point title | Anti-rubella IgG concentrations expressed as GMCs |
|-----------------|---|

End point description:

Anti-rubella IgG concentrations were expressed as GMCs in EU/mL. The analysis was performed on the Immunogenicity Set. Only the participants with anti-rubella IgG concentrations data available at the specified timepoint were reported in this outcome measure.

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

End point timeframe:

At Day 1 (before the first MR-VAC) and at Day 197 (28 days after the second MR-VAC vaccination)

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|--|--------------------------------------|---|---------------------------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 50 | 50 | 50 | 50 |
| Units: EU/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Day 1 (N=50, 50, 50, 50) | 1.0 (1.0 to 1.1) | 1.1 (1.0 to 1.2) | 1.2 (1.1 to 1.4) | 1.1 (1.0 to 1.2) |
| Day 197 (N=44, 42, 44, 45) | 91.1 (84.4 to 98.3) | 78.3 (68.2 to 89.8) | 85.1 (76.9 to 94.2) | 84.4 (77.7 to 91.7) |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants achieving anti-measles IgG concentrations of ≥ 150 international units per milliliter (IU/mL) and ≥ 200 IU/mL

| | |
|-----------------|--|
| End point title | Number of participants achieving anti-measles IgG concentrations of ≥ 150 international units per milliliter (IU/mL) and ≥ 200 IU/mL |
|-----------------|--|

End point description:

The analysis was performed on the Immunogenicity Set. Only the participants with anti-measles IgG concentrations data available at Day 197 were reported in this outcome measure.

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

End point timeframe:

At Day 197 (28 days after the second MR-VAC vaccination)

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|-----------------------------|--------------------------------------|---|---------------------------------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 44 | 42 | 44 | 45 |
| Units: Participants | | | | |
| ≥ 150 IU/L | 44 | 41 | 44 | 45 |
| ≥ 200 IU/L | 44 | 41 | 44 | 45 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants achieving anti-rubella IgG concentrations of ≥ 4 IU/mL and ≥ 10 IU/mL

| | |
|-----------------|--|
| End point title | Number of participants achieving anti-rubella IgG concentrations of ≥ 4 IU/mL and ≥ 10 IU/mL |
|-----------------|--|

End point description:

The analysis was performed on the Immunogenicity Set. Only the participants with anti-rubella IgG concentrations data available at Day 197 were reported in this outcome measure.

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

End point timeframe:

At Day 197 (28 days after the second MR-VAC vaccination)

| End point values | altSonflex1-2-3 Low Dose Group | altSonflex1-2-3 Medium Dose Group | altSonflex1-2-3 High Dose Group | Control Group |
|-----------------------------|--------------------------------------|---|---------------------------------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 44 | 42 | 44 | 45 |
| Units: Participants | | | | |
| ≥ 4 IU/mL | 44 | 42 | 44 | 45 |
| ≥ 10 IU/mL | 44 | 41 | 44 | 45 |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs: within 7 days after any vaccination. Unsolicited AEs: within 28 days after any vaccination. All-cause mortality, SAEs and abnormal laboratory parameters: from Day 1 until Day 197.

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

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 28.1 |

Reporting groups

| | |
|-----------------------|--------------------------|
| Reporting group title | altSonflex1-2-3 Low Dose |
|-----------------------|--------------------------|

Reporting group description:

Participants received 2 low doses of altSonflex1-2-3 along with the measles and rubella vaccine (MR-VAC) on Day 1 and Day 169.

| | |
|-----------------------|---------|
| Reporting group title | Control |
|-----------------------|---------|

Reporting group description:

Participants received 1 dose of the Typhibev on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169.

| | |
|-----------------------|---------------------------|
| Reporting group title | altSonflex1-2-3 High Dose |
|-----------------------|---------------------------|

Reporting group description:

Participants received 2 high doses of altSonflex1-2-3 along with MR-VAC on Day 1 and Day 169.

| | |
|-----------------------|-----------------------------|
| Reporting group title | altSonflex1-2-3 Medium Dose |
|-----------------------|-----------------------------|

Reporting group description:

Participants received 2 medium doses of altSonflex1-2-3 along with MR-VAC on Day 1 and Day 169.

| Serious adverse events | altSonflex1-2-3 Low Dose | Control | altSonflex1-2-3 High Dose |
|---|--------------------------|----------------|---------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 50 (0.00%) | 0 / 50 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Infections and infestations | | | |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 50 (0.00%) | 0 / 50 (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 |

| Serious adverse events | altSonflex1-2-3 Medium Dose | | |
|---|-----------------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

| | | | |
|---|----------------|--|--|
| Infections and infestations | | | |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 50 (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 | altSonflex1-2-3 Low Dose | Control | altSonflex1-2-3 High Dose |
|---|--------------------------|------------------|---------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 41 / 50 (82.00%) | 40 / 50 (80.00%) | 42 / 50 (84.00%) |
| Investigations | | | |
| White blood cell count decreased | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 50 (0.00%) | 1 / 50 (2.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 4 / 50 (8.00%) | 2 / 50 (4.00%) |
| occurrences (all) | 1 | 4 | 2 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 50 (0.00%) | 1 / 50 (2.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Platelet count increased | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 50 (0.00%) | 1 / 50 (2.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Injury, poisoning and procedural complications | | | |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 50 (0.00%) | 0 / 50 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Fontanelle bulging | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 50 (0.00%) | 0 / 50 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Administration site pain | | | |
| subjects affected / exposed | 15 / 50 (30.00%) | 15 / 50 (30.00%) | 23 / 50 (46.00%) |
| occurrences (all) | 22 | 16 | 28 |

| | | | |
|---|------------------------|------------------------|------------------------|
| Pyrexia subjects affected / exposed occurrences (all) | 12 / 50 (24.00%) 14 | 10 / 50 (20.00%) 13 | 9 / 50 (18.00%) 14 |
| Administration site swelling subjects affected / exposed occurrences (all) | 12 / 50 (24.00%) 14 | 8 / 50 (16.00%) 8 | 18 / 50 (36.00%) 19 |
| Feeling hot subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | 0 / 50 (0.00%) 0 | 1 / 50 (2.00%) 1 |
| Administration site erythema subjects affected / exposed occurrences (all) | 8 / 50 (16.00%) 10 | 7 / 50 (14.00%) 7 | 10 / 50 (20.00%) 13 |
| Blood and lymphatic system disorders Neutropenia subjects affected / exposed occurrences (all) | 3 / 50 (6.00%) 3 | 2 / 50 (4.00%) 2 | 1 / 50 (2.00%) 1 |
| Eye disorders Eye discharge subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | 0 / 50 (0.00%) 0 | 0 / 50 (0.00%) 0 |
| Conjunctivitis allergic subjects affected / exposed occurrences (all) | 0 / 50 (0.00%) 0 | 0 / 50 (0.00%) 0 | 0 / 50 (0.00%) 0 |
| Gastrointestinal disorders Teething subjects affected / exposed occurrences (all) | 0 / 50 (0.00%) 0 | 0 / 50 (0.00%) 0 | 0 / 50 (0.00%) 0 |
| Constipation subjects affected / exposed occurrences (all) | 0 / 50 (0.00%) 0 | 0 / 50 (0.00%) 0 | 1 / 50 (2.00%) 1 |
| Vomiting subjects affected / exposed occurrences (all) | 2 / 50 (4.00%) 2 | 0 / 50 (0.00%) 0 | 1 / 50 (2.00%) 1 |
| Diarrhoea subjects affected / exposed occurrences (all) | 3 / 50 (6.00%) 3 | 3 / 50 (6.00%) 3 | 3 / 50 (6.00%) 3 |
| Respiratory, thoracic and mediastinal | | | |

| | | | |
|--|-----------------|----------------|----------------|
| disorders | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 50 (0.00%) | 2 / 50 (4.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Rhinitis allergic | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 1 / 50 (2.00%) | 0 / 50 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Urticaria | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 50 (0.00%) | 0 / 50 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 50 (0.00%) | 0 / 50 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 1 / 50 (2.00%) | 0 / 50 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dermatitis | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 50 (0.00%) | 0 / 50 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dermatitis allergic | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 2 / 50 (4.00%) | 1 / 50 (2.00%) |
| occurrences (all) | 0 | 2 | 1 |
| Rash | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 1 / 50 (2.00%) | 0 / 50 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Psychiatric disorders | | | |
| Irritability | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 50 (0.00%) | 1 / 50 (2.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Infections and infestations | | | |
| Amoebiasis | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 50 (0.00%) | 3 / 50 (6.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Tonsillitis | | | |
| subjects affected / exposed | 5 / 50 (10.00%) | 1 / 50 (2.00%) | 4 / 50 (8.00%) |
| occurrences (all) | 5 | 1 | 4 |

| | | | |
|-----------------------------------|-----------------|------------------|-----------------|
| Gastroenteritis | | | |
| subjects affected / exposed | 4 / 50 (8.00%) | 6 / 50 (12.00%) | 2 / 50 (4.00%) |
| occurrences (all) | 4 | 6 | 2 |
| Rhinitis | | | |
| subjects affected / exposed | 5 / 50 (10.00%) | 12 / 50 (24.00%) | 8 / 50 (16.00%) |
| occurrences (all) | 5 | 13 | 8 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 8 / 50 (16.00%) | 13 / 50 (26.00%) | 6 / 50 (12.00%) |
| occurrences (all) | 10 | 13 | 6 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 2 / 50 (4.00%) | 1 / 50 (2.00%) | 0 / 50 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Foot and mouth disease | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 50 (0.00%) | 0 / 50 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Escherichia infection | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 50 (0.00%) | 0 / 50 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 50 (0.00%) | 0 / 50 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Malaria | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 50 (0.00%) | 0 / 50 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 1 / 50 (2.00%) | 0 / 50 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 2 / 50 (4.00%) | 0 / 50 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 1 / 50 (2.00%) | 1 / 50 (2.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Pulmonary tuberculosis | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 50 (0.00%) | 3 / 50 (6.00%) |
| occurrences (all) | 0 | 0 | 3 |

| | | | |
|---|---------------------|---------------------|---------------------|
| Rotavirus infection subjects affected / exposed occurrences (all) | 0 / 50 (0.00%) 0 | 0 / 50 (0.00%) 0 | 0 / 50 (0.00%) 0 |
| Otitis media acute subjects affected / exposed occurrences (all) | 0 / 50 (0.00%) 0 | 1 / 50 (2.00%) 1 | 0 / 50 (0.00%) 0 |
| Norovirus infection subjects affected / exposed occurrences (all) | 0 / 50 (0.00%) 0 | 0 / 50 (0.00%) 0 | 0 / 50 (0.00%) 0 |
| Scabies subjects affected / exposed occurrences (all) | 0 / 50 (0.00%) 0 | 0 / 50 (0.00%) 0 | 1 / 50 (2.00%) 1 |
| Metabolism and nutrition disorders Dehydration subjects affected / exposed occurrences (all) | 0 / 50 (0.00%) 0 | 2 / 50 (4.00%) 2 | 0 / 50 (0.00%) 0 |

| | | | |
|--|--------------------------------|--|--|
| Non-serious adverse events | altSonflex1-2-3 Medium Dose | | |
| Total subjects affected by non-serious adverse events subjects affected / exposed | 35 / 50 (70.00%) | | |
| Investigations White blood cell count decreased subjects affected / exposed occurrences (all) | 0 / 50 (0.00%) 0 | | |
| Haemoglobin decreased subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | | |
| Alanine aminotransferase increased subjects affected / exposed occurrences (all) | 0 / 50 (0.00%) 0 | | |
| Platelet count increased subjects affected / exposed occurrences (all) | 0 / 50 (0.00%) 0 | | |
| Injury, poisoning and procedural complications Thermal burn | | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | | |
| Nervous system disorders Fontanelle bulging subjects affected / exposed occurrences (all) | 0 / 50 (0.00%) 0 | | |
| General disorders and administration site conditions Administration site pain subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all) Administration site swelling subjects affected / exposed occurrences (all) Feeling hot subjects affected / exposed occurrences (all) Administration site erythema subjects affected / exposed occurrences (all) | 19 / 50 (38.00%) 27 12 / 50 (24.00%) 16 13 / 50 (26.00%) 19 0 / 50 (0.00%) 0 7 / 50 (14.00%) 9 | | |
| Blood and lymphatic system disorders Neutropenia subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | | |
| Eye disorders Eye discharge subjects affected / exposed occurrences (all) Conjunctivitis allergic subjects affected / exposed occurrences (all) | 0 / 50 (0.00%) 0 1 / 50 (2.00%) 1 | | |
| Gastrointestinal disorders Teething | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 1 / 50 (2.00%) | | |
| occurrences (all) | 1 | | |
| Constipation | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | | |
| occurrences (all) | 0 | | |
| Diarrhoea | | | |
| subjects affected / exposed | 4 / 50 (8.00%) | | |
| occurrences (all) | 4 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 2 / 50 (4.00%) | | |
| occurrences (all) | 2 | | |
| Rhinitis allergic | | | |
| subjects affected / exposed | 2 / 50 (4.00%) | | |
| occurrences (all) | 3 | | |
| Skin and subcutaneous tissue disorders | | | |
| Urticaria | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | | |
| occurrences (all) | 1 | | |
| Pruritus | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | | |
| occurrences (all) | 1 | | |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dermatitis allergic | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash | | | |

| | | | |
|---|----------------------|--|--|
| subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | | |
| Psychiatric disorders Irritability subjects affected / exposed occurrences (all) | 0 / 50 (0.00%) 0 | | |
| Infections and infestations Amoebiasis subjects affected / exposed occurrences (all) | 4 / 50 (8.00%) 4 | | |
| Tonsillitis subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | | |
| Gastroenteritis subjects affected / exposed occurrences (all) | 5 / 50 (10.00%) 5 | | |
| Rhinitis subjects affected / exposed occurrences (all) | 8 / 50 (16.00%) 8 | | |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 8 / 50 (16.00%) 8 | | |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | | |
| Foot and mouth disease subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | | |
| Escherichia infection subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | | |
| Conjunctivitis subjects affected / exposed occurrences (all) | 0 / 50 (0.00%) 0 | | |
| Malaria | | | |

| | | | |
|------------------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 50 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pharyngitis | | | |
| subjects affected / exposed | 2 / 50 (4.00%) | | |
| occurrences (all) | 2 | | |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | | |
| occurrences (all) | 0 | | |
| Otitis media | | | |
| subjects affected / exposed | 2 / 50 (4.00%) | | |
| occurrences (all) | 2 | | |
| Pulmonary tuberculosis | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rotavirus infection | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | | |
| occurrences (all) | 1 | | |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | | |
| occurrences (all) | 0 | | |
| Norovirus infection | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | | |
| occurrences (all) | 1 | | |
| Scabies | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | | |
| occurrences (all) | 0 | | |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | | |
| occurrences (all) | 0 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---------------|---|
| 19 April 2024 | The amendment has been prepared to improve safety monitoring of participants by modifying the creatinine grading scale based on normal reference range that better represents the population being evaluated and by introducing blood urea, sodium, and potassium testing to ensure further monitoring of the renal function. Endpoints have been added to capture the potential impact of vaccination on the respective endpoints as a broader evaluation of the vaccine profile. Other administrative changes have been made as requested by ethics committee reviewer and updated internal company guidance. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported