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
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. S. sonnei, S. flexneri 1b, S. flexneri 2a, and S. flexneri 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 ≥38.0°Celsius (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 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 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 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	12 / 50 (24.00%)	10 / 50 (20.00%)	9 / 50 (18.00%)
occurrences (all)	14	13	14
Administration site swelling			
subjects affected / exposed	12 / 50 (24.00%)	8 / 50 (16.00%)	18 / 50 (36.00%)
occurrences (all)	14	8	19
Feeling hot			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	1	0	1
Administration site erythema			
subjects affected / exposed	8 / 50 (16.00%)	7 / 50 (14.00%)	10 / 50 (20.00%)
occurrences (all)	10	7	13
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	3 / 50 (6.00%)	2 / 50 (4.00%)	1 / 50 (2.00%)
occurrences (all)	3	2	1
Eye disorders			
Eye discharge			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Teething			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	2 / 50 (4.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	2	0	1
Diarrhoea			
subjects affected / exposed	3 / 50 (6.00%)	3 / 50 (6.00%)	3 / 50 (6.00%)
occurrences (all)	3	3	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	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Norovirus infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Scabies			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 50 (0.00%)	2 / 50 (4.00%)	0 / 50 (0.00%)
occurrences (all)	0	2	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	0 / 50 (0.00%)		
occurrences (all)	0		
Haemoglobin decreased			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
Alanine aminotransferase increased			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Platelet count increased			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	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	1 / 50 (2.00%)		
occurrences (all)	1		
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Amoebiasis			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	4		
Tonsillitis			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
Gastroenteritis			
subjects affected / exposed	5 / 50 (10.00%)		
occurrences (all)	5		
Rhinitis			
subjects affected / exposed	8 / 50 (16.00%)		
occurrences (all)	8		
Upper respiratory tract infection			
subjects affected / exposed	8 / 50 (16.00%)		
occurrences (all)	8		
Nasopharyngitis			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
Foot and mouth disease			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
Escherichia infection			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
Conjunctivitis			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	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