



Clinical trial results:

Phase 2 Clinical Trial of the BioMed rTSST-1 Variant Vaccine in Healthy Adults

Summary

EudraCT number	2015-003714-24
Trial protocol	AT
Global end of trial date	06 February 2020

Results information

Result version number	v1 (current)
This version publication date	13 December 2021
First version publication date	13 December 2021

Trial information

Trial identification

Sponsor protocol code	0515
-----------------------	------

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Biomedizinische Forschung & Bio-Produkte AG
Sponsor organisation address	Lazarettgasse 19, Vienna, Austria,
Public contact	CEO, Biomedizinische Forschung & Bio-Produkte AG, 43 1408109111, office@biomed-research.at
Scientific contact	CEO, Biomedizinische Forschung & Bio-Produkte AG, 43 1408109111, office@biomed-research.at

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	01 July 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 February 2020
Global end of trial reached?	Yes
Global end of trial date	06 February 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Safety and tolerability of two doses of the BioMed rTSST-1 Vaccine after one to three vaccinations in healthy adults

Protection of trial subjects:

Absence of clinically relevant adverse events required for the two doses tested.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2016
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	Austria: 140
Worldwide total number of subjects	140
EEA total number of subjects	140

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	140
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Signed informed consent obtained before any trial-related activities

Men or women aged >18 and <64 years

Normal findings in medical history and physical examination

Period 1

Period 1 title	Phase 2 rTSST-1v Clinical Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Arms

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

Arm title	rTSST-1 Variant Candidate Vaccine 10 µg
------------------	---

Arm description:

Number of immunisations: 1

Arm type	Experimental
Investigational medicinal product name	rTSST-1v
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

10 µg

Arm title	rTSST-1 Variant Candidate Vaccine 10 µg
------------------	---

Arm description:

Number of immunisations: 2

Arm type	Experimental
Investigational medicinal product name	rTSST-1v
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

10 µg

Arm title	rTSST-1 Variant Candidate Vaccine 10 µg
------------------	---

Arm description:

Number of immunisations: 3

Arm type	Experimental
Investigational medicinal product name	rTSST-1v
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

10 µg

Arm title	rTSST-1 Variant Candidate Vaccine 100 µg
------------------	--

Arm description:

Number of immunisations: 1

Arm type	Experimental
----------	--------------

Investigational medicinal product name	rTSST-1v
--	----------

Investigational medicinal product code	
--	--

Other name	
------------	--

Pharmaceutical forms	Suspension for injection
----------------------	--------------------------

Routes of administration	Intramuscular use
--------------------------	-------------------

Dosage and administration details:

100 µg

Arm title	rTSST-1 Variant Candidate Vaccine 100 µg
------------------	--

Arm description:

Number of immunisations: 2

Arm type	Experimental
----------	--------------

Investigational medicinal product name	rTSST-1v
--	----------

Investigational medicinal product code	
--	--

Other name	
------------	--

Pharmaceutical forms	Suspension for injection
----------------------	--------------------------

Routes of administration	Intramuscular use
--------------------------	-------------------

Dosage and administration details:

100 µg

Arm title	rTSST-1 Variant Candidate Vaccine 100 µg
------------------	--

Arm description:

Number of immunisations: 3

Arm type	Experimental
----------	--------------

Investigational medicinal product name	rTSST-1v
--	----------

Investigational medicinal product code	
--	--

Other name	
------------	--

Pharmaceutical forms	Suspension for injection
----------------------	--------------------------

Routes of administration	Intramuscular use
--------------------------	-------------------

Dosage and administration details:

100 µg

Arm title	Placebo
------------------	---------

Arm description:

Aluminium Hydroxide

Arm type	Placebo
----------	---------

Investigational medicinal product name	Aluminium Hydroxide
--	---------------------

Investigational medicinal product code	
--	--

Other name	
------------	--

Pharmaceutical forms	Solution for injection
----------------------	------------------------

Routes of administration	Intramuscular use
--------------------------	-------------------

Dosage and administration details:

1 mg

Number of subjects in period 1	rTSST-1 Variant Candidate Vaccine 10 µg	rTSST-1 Variant Candidate Vaccine 10 µg	rTSST-1 Variant Candidate Vaccine 10 µg
Started	20	20	20
Completed	14	15	16
Not completed	6	5	4
Adverse event, non-fatal	-	-	-
Lost to follow-up	6	5	4

Number of subjects in period 1	rTSST-1 Variant Candidate Vaccine 100 µg	rTSST-1 Variant Candidate Vaccine 100 µg	rTSST-1 Variant Candidate Vaccine 100 µg
Started	20	20	20
Completed	15	13	13
Not completed	5	7	7
Adverse event, non-fatal	-	1	-
Lost to follow-up	5	6	7

Number of subjects in period 1	Placebo
Started	20
Completed	16
Not completed	4
Adverse event, non-fatal	-
Lost to follow-up	4

Baseline characteristics

Reporting groups

Reporting group title	Phase 2 rTSST-1v Clinical Trial
-----------------------	---------------------------------

Reporting group description: -

Reporting group values	Phase 2 rTSST-1v Clinical Trial	Total	
Number of subjects	140	140	
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)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	140	140	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	31.9		
standard deviation	± 11.2	-	
Gender categorical Units: Subjects			
Female	49	49	
Male	91	91	

Subject analysis sets

Subject analysis set title	Safety analysis
----------------------------	-----------------

Subject analysis set type	Safety analysis
---------------------------	-----------------

Subject analysis set description:

All subjects entering the study and randomised were included in the safety analysis set.

Subject analysis set title	Immunogenicity analysis
----------------------------	-------------------------

Subject analysis set type	Per protocol
---------------------------	--------------

Subject analysis set description:

The PP population was the primary study population for the immunogenicity analysis

Reporting group values	Safety analysis	Immunogenicity analysis	
Number of subjects	140	126	
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)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	140	126	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	
Gender categorical			
Units: Subjects			
Female			
Male			

End points

End points reporting groups

Reporting group title	rTSST-1 Variant Candidate Vaccine 10 µg
Reporting group description:	
Number of immunisations:	1
Reporting group title	rTSST-1 Variant Candidate Vaccine 10 µg
Reporting group description:	
Number of immunisations:	2
Reporting group title	rTSST-1 Variant Candidate Vaccine 10 µg
Reporting group description:	
Number of immunisations:	3
Reporting group title	rTSST-1 Variant Candidate Vaccine 100 µg
Reporting group description:	
Number of immunisations:	1
Reporting group title	rTSST-1 Variant Candidate Vaccine 100 µg
Reporting group description:	
Number of immunisations:	2
Reporting group title	rTSST-1 Variant Candidate Vaccine 100 µg
Reporting group description:	
Number of immunisations:	3
Reporting group title	Placebo
Reporting group description:	Aluminium Hydroxide
Subject analysis set title	Safety analysis
Subject analysis set type	Safety analysis
Subject analysis set description:	All subjects entering the study and randomised were included in the safety analysis set.
Subject analysis set title	Immunogenicity analysis
Subject analysis set type	Per protocol
Subject analysis set description:	The PP population was the primary study population for the immunogenicity analysis

Primary: Number of subjects with adverse events

End point title	Number of subjects with adverse events
End point description:	
End point type	Primary
End point timeframe:	Follow ups were 3, 6, 12, 15, 18, 21, 24, and 27 months

End point values	rTSST-1 Variant Candidate Vaccine 10 µg	rTSST-1 Variant Candidate Vaccine 10 µg	rTSST-1 Variant Candidate Vaccine 10 µg	rTSST-1 Variant Candidate Vaccine 100 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20 ^[1]	20 ^[2]	20 ^[3]	20 ^[4]
Units: 140	20	18	19	20

Notes:

- [1] - Number of events: 165
- [2] - Number of events: 145
- [3] - Number of events: 171
- [4] - Number of events: 248

End point values	rTSST-1 Variant Candidate Vaccine 100 µg	rTSST-1 Variant Candidate Vaccine 100 µg	Placebo	Safety analysis
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	20 ^[5]	20 ^[6]	20 ^[7]	140 ^[8]
Units: 140	20	16	20	133

Notes:

- [5] - Number of events: 193
- [6] - Number of events: 182
- [7] - Number of events: 166
- [8] - Number of events: 1270

Statistical analyses

Statistical analysis title	Descriptive statistics
Comparison groups	rTSST-1 Variant Candidate Vaccine 10 µg v rTSST-1 Variant Candidate Vaccine 10 µg v rTSST-1 Variant Candidate Vaccine 10 µg v rTSST-1 Variant Candidate Vaccine 100 µg v rTSST-1 Variant Candidate Vaccine 100 µg v rTSST-1 Variant Candidate Vaccine 100 µg v Placebo
Number of subjects included in analysis	140
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0
Method	Not done

Primary: Number of subjects with seroconversion

End point title	Number of subjects with seroconversion
End point description:	
End point type	Primary
End point timeframe:	
18 months follow up	

End point values	rTSST-1 Variant Candidate Vaccine 10 µg	rTSST-1 Variant Candidate Vaccine 10 µg	rTSST-1 Variant Candidate Vaccine 10 µg	rTSST-1 Variant Candidate Vaccine 100 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18 ^[9]	17 ^[10]	19 ^[11]	20 ^[12]
Units: 126	10	12	13	14

Notes:

- [9] - PP population, 18 months follow up
- [10] - PP population, 18 months follow up
- [11] - PP population, 18 months follow up
- [12] - PP population, 18 months follow up

End point values	rTSST-1 Variant Candidate Vaccine 100 µg	rTSST-1 Variant Candidate Vaccine 100 µg	Placebo	Immunogenicity analysis
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	17 ^[13]	16 ^[14]	19 ^[15]	
Units: 126	12	12	0	73

Notes:

- [13] - PP population, 18 months follow up
- [14] - PP population, 18 months follow up
- [15] - PP population, 18 months follow up

Statistical analyses

Statistical analysis title	Laboratory parameters
-----------------------------------	-----------------------

Statistical analysis description:

Descriptive statistics. Tabulation of laboratory parameters over time by treatment group and by subjects.

Comparison groups	rTSST-1 Variant Candidate Vaccine 10 µg v rTSST-1 Variant Candidate Vaccine 10 µg v rTSST-1 Variant Candidate Vaccine 10 µg v rTSST-1 Variant Candidate Vaccine 100 µg v rTSST-1 Variant Candidate Vaccine 100 µg v Placebo
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0
Method	Not done

Secondary: Number of subjects with seroconversion

End point title	Number of subjects with seroconversion
-----------------	--

End point description:

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

End point timeframe:

12 months

End point values	rTSST-1 Variant Candidate Vaccine 10 µg	rTSST-1 Variant Candidate Vaccine 10 µg	rTSST-1 Variant Candidate Vaccine 10 µg	rTSST-1 Variant Candidate Vaccine 100 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18 ^[16]	17 ^[17]	19 ^[18]	20 ^[19]
Units: 126	13	15	17	17

Notes:

[16] - PP population, 12 months

[17] - PP population, 12 months

[18] - PP population, 12 months

[19] - PP population, 12 months

End point values	rTSST-1 Variant Candidate Vaccine 100 µg	rTSST-1 Variant Candidate Vaccine 100 µg	Placebo	Immunogenicity analysis
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	17 ^[20]	16 ^[21]	19 ^[22]	126 ^[23]
Units: 126	13	15	0	90

Notes:

[20] - PP population, 12 months

[21] - PP population, 12 months

[22] - PP population, 12 months

[23] - PP population (including placebo), 12 months

Statistical analyses

Statistical analysis title	Laboratory parameters
Statistical analysis description:	
Descriptive statistics. Tabulation of laboratory parameters over time by treatment group and by subjects.	
Comparison groups	rTSST-1 Variant Candidate Vaccine 10 µg v rTSST-1 Variant Candidate Vaccine 10 µg v rTSST-1 Variant Candidate Vaccine 10 µg v rTSST-1 Variant Candidate Vaccine 100 µg v rTSST-1 Variant Candidate Vaccine 100 µg v rTSST-1 Variant Candidate Vaccine 100 µg v Placebo
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0
Method	Not done

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Follow ups were 3, 6, 12, 15, 18, 21, 24, and 27 months

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

Dictionary used

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

Dictionary version	18.0
--------------------	------

Reporting groups

Reporting group title	rTSST-1 Variant Candidate Vaccine 10 µg
-----------------------	---

Reporting group description:

Number of immunisations: 1

Reporting group title	rTSST-1 Variant Candidate Vaccine 10 µg
-----------------------	---

Reporting group description:

Number of immunisations: 2

Reporting group title	rTSST-1 Variant Candidate Vaccine 10 µg
-----------------------	---

Reporting group description:

Number of immunisations: 3

Reporting group title	rTSST-1 Variant Candidate Vaccine 100 µg
-----------------------	--

Reporting group description:

Number of immunisations: 1

Reporting group title	rTSST-1 Variant Candidate Vaccine 100 µg
-----------------------	--

Reporting group description:

Number of immunisations: 2

Reporting group title	rTSST-1 Variant Candidate Vaccine 100 µg
-----------------------	--

Reporting group description:

Number of immunisations: 3

Reporting group title	Placebo
-----------------------	---------

Reporting group description:

Aluminium Hydroxide

Serious adverse events	rTSST-1 Variant Candidate Vaccine 10 µg	rTSST-1 Variant Candidate Vaccine 10 µg	rTSST-1 Variant Candidate Vaccine 10 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Investigations			
Hysteroscopy			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and			

unspecified (incl cysts and polyps)			
Thyroid cancer			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (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
Injury, poisoning and procedural complications			
Gastrointestinal anastomotic complication			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Congenital genitourinary abnormality			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abdominoplasty			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric bypass			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus operation			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal septal operation			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shoulder operation			

subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus operation			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	rTSST-1 Variant Candidate Vaccine 100 µg	rTSST-1 Variant Candidate Vaccine 100 µg	rTSST-1 Variant Candidate Vaccine 100 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 20 (15.00%)	3 / 20 (15.00%)	0 / 20 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Investigations			
Hysteroscopy			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Thyroid cancer			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Gastrointestinal anastomotic complication			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic			

disorders			
Congenital genitourinary abnormality			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (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
Surgical and medical procedures			
Abdominoplasty			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric bypass			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus operation			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal septal operation			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (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
Shoulder operation			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus operation			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (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
Immune system disorders			
Anaphylactic reaction			

subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Investigations			
Hysteroscopy			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Thyroid cancer			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Gastrointestinal anastomotic complication			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Congenital genitourinary abnormality			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Abdominoplasty			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Gastric bypass			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meniscus operation			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasal septal operation			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shoulder operation			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinus operation			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 20 (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: 0 %

Non-serious adverse events	rTSST-1 Variant Candidate Vaccine 10 µg	rTSST-1 Variant Candidate Vaccine 10 µg	rTSST-1 Variant Candidate Vaccine 10 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 20 (100.00%)	18 / 20 (90.00%)	19 / 20 (95.00%)
Injury, poisoning and procedural complications			

General symptom subjects affected / exposed occurrences (all)	4 / 20 (20.00%) 4	3 / 20 (15.00%) 4	1 / 20 (5.00%) 1
Surgical and medical procedures General symptom subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	1 / 20 (5.00%) 1	0 / 20 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	6 / 20 (30.00%) 24	9 / 20 (45.00%) 25	8 / 20 (40.00%) 27
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all) Influenza like illness subjects affected / exposed occurrences (all)	6 / 20 (30.00%) 18 2 / 20 (10.00%) 4	7 / 20 (35.00%) 10 6 / 20 (30.00%) 7	4 / 20 (20.00%) 8 3 / 20 (15.00%) 6
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2	5 / 20 (25.00%) 6	4 / 20 (20.00%) 6
Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1	0 / 20 (0.00%) 0	0 / 20 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1	0 / 20 (0.00%) 0	4 / 20 (20.00%) 4
Skin and subcutaneous tissue disorders General symptom subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2	3 / 20 (15.00%) 3	4 / 20 (20.00%) 4
Musculoskeletal and connective tissue disorders			

Myalgia subjects affected / exposed occurrences (all)	3 / 20 (15.00%) 3	4 / 20 (20.00%) 5	4 / 20 (20.00%) 4
Back pain subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	1 / 20 (5.00%) 1	1 / 20 (5.00%) 1
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	5 / 20 (25.00%) 7	10 / 20 (50.00%) 18	6 / 20 (30.00%) 9

Non-serious adverse events	rTSST-1 Variant Candidate Vaccine 100 µg	rTSST-1 Variant Candidate Vaccine 100 µg	rTSST-1 Variant Candidate Vaccine 100 µg
Total subjects affected by non-serious adverse events subjects affected / exposed	20 / 20 (100.00%)	20 / 20 (100.00%)	16 / 20 (80.00%)
Injury, poisoning and procedural complications General symptom subjects affected / exposed occurrences (all)	4 / 20 (20.00%) 4	6 / 20 (30.00%) 8	3 / 20 (15.00%) 5
Surgical and medical procedures General symptom subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2	3 / 20 (15.00%) 5	0 / 20 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	13 / 20 (65.00%) 75	11 / 20 (55.00%) 30	10 / 20 (50.00%) 21
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	8 / 20 (40.00%) 15	5 / 20 (25.00%) 9	8 / 20 (40.00%) 10
Influenza like illness subjects affected / exposed occurrences (all)	8 / 20 (40.00%) 12	6 / 20 (30.00%) 12	8 / 20 (40.00%) 9
Gastrointestinal disorders Nausea			

subjects affected / exposed occurrences (all)	5 / 20 (25.00%) 10	1 / 20 (5.00%) 1	3 / 20 (15.00%) 4
Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	1 / 20 (5.00%) 2	4 / 20 (20.00%) 10
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all)	3 / 20 (15.00%) 3	2 / 20 (10.00%) 2	0 / 20 (0.00%) 0
Skin and subcutaneous tissue disorders General symptom subjects affected / exposed occurrences (all)	4 / 20 (20.00%) 5	6 / 20 (30.00%) 11	3 / 20 (15.00%) 3
Musculoskeletal and connective tissue disorders Myalgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all)	6 / 20 (30.00%) 6 4 / 20 (20.00%) 5	6 / 20 (30.00%) 9 1 / 20 (5.00%) 1	5 / 20 (25.00%) 9 2 / 20 (10.00%) 2
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	5 / 20 (25.00%) 6	7 / 20 (35.00%) 10	9 / 20 (45.00%) 16

Non-serious adverse events	Placebo		
Total subjects affected by non-serious adverse events subjects affected / exposed	20 / 20 (100.00%)		
Injury, poisoning and procedural complications General symptom subjects affected / exposed occurrences (all)	4 / 20 (20.00%) 4		
Surgical and medical procedures General symptom			

subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	9 / 20 (45.00%) 40		
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all) Influenza like illness subjects affected / exposed occurrences (all)	8 / 20 (40.00%) 16 4 / 20 (20.00%) 6		
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	3 / 20 (15.00%) 4		
Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 0		
Skin and subcutaneous tissue disorders General symptom subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2		
Musculoskeletal and connective tissue disorders Myalgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all)	5 / 20 (25.00%) 8 0 / 20 (0.00%) 0		

Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	6 / 20 (30.00%) 10		
--	-----------------------	--	--

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

None reported

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/27296693>