Clinical trial results:
A Phase 2b Randomized, Double-blind Study to Evaluate the Efficacy of MEDI7510 for the Prevention of Acute Respiratory Syncytial Virus-associated Respiratory Illness in Older Adults

Summary

EudraCT number	2015-002758-11
Trial protocol	LT LV EE
Global end of trial date	09 September 2016

Results information

Result version number	v1 (current)
This version publication date	23 August 2017
First version publication date	23 August 2017

Trial information

Trial identification

Sponsor protocol code	D4420C00005

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02508194
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	MedImmune, LLC
Sponsor organisation address	One MedImmune Way, Gaithersburg, United States, 20878
Public contact	AstraZeneca Clinical Study Information Center, AstraZeneca, +1 3013980000, clinicaltrialenquiries@medimmune.com
Scientific contact	AstraZeneca Clinical Study Information Center, AstraZeneca, +1 3013980000, clinicaltrialenquiries@medimmune.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 September 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 September 2016
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of a single intramuscular (IM) dose of MEDI7510 for the prevention of acute respiratory syncytial virus-associated respiratory illness (ARA-RI) in adults greater than or equal to (>=) 60 years of age in Season 1 of dosing.

Protection of trial subjects:

The conduct of this clinical study met all local and regulatory requirements. The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and are consistent with International Conference on Harmonization guideline: Good Clinical Practice, and applicable regulatory requirements. Participants signed an informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. Only investigators qualified by training and experience were selected as appropriate experts to investigate the study drug.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 September 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 23
Country: Number of subjects enrolled	Chile: 75
Country: Number of subjects enrolled	Estonia: 87
Country: Number of subjects enrolled	Latvia: 7
Country: Number of subjects enrolled	South Africa: 224
Country: Number of subjects enrolled	United States: 1447
Country: Number of subjects enrolled	Lithuania: 37
Worldwide total number of subjects	1900
EEA total number of subjects	131

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)	674
From 65 to 84 years	1199
85 years and over	27

Subject disposition

Recruitment

Recruitment details:

A total of 1900 participants were randomized and participated in the study at 60 sites in 7 countries.

Pre-assignment

Screening details:

A total of 2,044 participants were screened, of which 144 participants were screen failures and 1900 participants were randomized in the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo + Inactivated Influenza Vaccine (IIV)

Arm description:

Participants received a single IM injection of placebo (matched with MEDI7510) in one arm and single IM injection of IIV in the contralateral arm.

Arm type	Active comparator
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	Sterile saline
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received a single IM injection of placebo (matched with MEDI7510) in the arm.

Investigational medicinal product name	IIV
Investigational medicinal product code	
Other name	Marketed Inactivated Influenza Vaccine
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received a single IM injection of IIV in the contralateral arm.

Arm title	MEDI7510 + IIV

Arm description:

Participants received a single IM injection of MEDI7510 in one arm and single IM injection of IIV in the contralateral arm.

Arm type	Experimental
Investigational medicinal product name	MEDI7510
Investigational medicinal product code	
Other name	Respiratory Syncytial Virus soluble fusion (RSV sF) protein antigen plus glucopyranosyl lipid A in stable emulsion (GLA-SE) adjuvant
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received a single IM injection of MEDI7510 in the arm.

Investigational medicinal product name	IIV
Investigational medicinal product code	
Other name	Marketed Inactivated Influenza Vaccine
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received a single IM injection of IIV in the contralateral arm.

Number of subjects in period 1	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV
Started	949	951
Completed	897	907
Not completed	52	44
Consent withdrawn by subject	20	18
Error in Randomization	1	3
Death	5	3
Lost to follow-up	25	18
PI Decision	1	2

Baseline characteristics

Reporting groups	
Reporting group title	Placebo + Inactivated Influenza Vaccine (IIV)
Reporting group description:	
Participants received a single IM injection of placebo (matched with MEDI7510) in one arm and single IM injection of IIV in the contralateral arm.	
Reporting group title	MEDI7510 + IIV
Reporting group description:	
Participants received a single IM injection of MEDI7510 in one arm and single IM injection of IIV in the contralateral arm.	

Reporting group values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV	Total
Number of subjects	949	951	1900
Age categorical Units: Subjects			
Adults (18-64 years)	332	342	674
From 65-84 years	603	596	1199
85 years and over	14	13	27
Age Continuous Units: Years			
arithmetic mean	68.1	68.1	
standard deviation	± 6.2	± 6.3	-
Gender, Male/Female Units: Subjects			
Female	587	530	1117
Male	362	421	783

End points

End points reporting groups

Reporting group title	Placebo + Inactivated Influenza Vaccine (IIV)
Reporting group description:	
Participants received a single IM injection of placebo (matched with MEDI7510) in one arm and single IM injection of IIV in the contralateral arm.	
Reporting group title	MEDI7510 + IIV
Reporting group description:	
Participants received a single IM injection of MEDI7510 in one arm and single IM injection of IIV in the contralateral arm.	

Primary: Percentage of Participants who had the First Episode of ARA-RI During RSV Surveillance Period in Season 1

End point title	Percentage of Participants who had the First Episode of ARA-RI During RSV Surveillance Period in Season 1
End point description:	
ARA-RI was defined as an event in which a participant met specified clinical criteria and the event was laboratory-confirmed to be RSV-related. The specified clinical criteria included a minimum of 1 symptom from any 2 of the 3 symptom columns: one symptom from upper respiratory symptom column and one symptom from lower respiratory symptom column; one symptom from upper respiratory symptom column and one symptom from systemic symptom column; or one symptom from lower respiratory column and one from systemic symptom column and laboratory confirmation of RSV on at least 1 sample obtained between Day 1 to Day 8 of illness. Per-protocol population: All Participants in the As-treated Population (ATP) who were followed for qualifying symptoms for RSV until the end of the RSV surveillance period.	
End point type	Primary
End point timeframe:	
Day 14 after dosing through end of surveillance period	

End point values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	935	931		
Units: Percentage of Participants				
number (not applicable)	1.6	1.7		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
2 sided 90 percent (%) confidence interval (CI) was used to compare vaccine efficacy (VE). VE = ([1 - relative risk (RR)] *100%), where RR was the RR of ARA-RI in the MEDI7510+IIV group compared with the placebo+IIV group. A lower bound of the 90% CI greater than (>) 0% would demonstrate the efficacy of MEDI7510. The CI was estimated by an exact conditional method.	
Comparison groups	Placebo + Inactivated Influenza Vaccine (IIV) v MEDI7510 +

	IIV
Number of subjects included in analysis	1866
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine efficacy
Point estimate	-7.1
Confidence interval	
level	90 %
sides	2-sided
lower limit	-106.9
upper limit	44.3

Secondary: Percentage of Participants who had a RSV Polymerase Chain Reaction (PCR)-Positive Respiratory Illness During the RSV Surveillance Period in Season 1

End point title	Percentage of Participants who had a RSV Polymerase Chain Reaction (PCR)-Positive Respiratory Illness During the RSV Surveillance Period in Season 1

End point description:

Detection of RSV was done by PCR method by using any respiratory sample. The incidence of RSV PCR-positive respiratory illness during the RSV surveillance period was evaluated. Per-protocol population: All participants in the ATP who were followed for qualifying symptoms for RSV until the end of the RSV surveillance period.

End point type	Secondary

End point timeframe:

Day 14 after dosing through end of surveillance period

End point values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	935	931		
Units: Percentage of participants				
number (not applicable)	1.6	1.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Responses (GMRs) of Serum Antibodies Against RSV by Anti-Fusion Protein (F) Immunoglobulin G (IgG) Assay

End point title	Geometric Mean Responses (GMRs) of Serum Antibodies Against RSV by Anti-Fusion Protein (F) Immunoglobulin G (IgG) Assay

End point description:

Anti-F IgG antibodies were determined by a multiplex IgG assay developed on the Meso Scale discovery platform. GMR was calculated as: anti-log2[mean(log2 xi)], where xi is the assay result for participant i.

Immunogenicity population for MEDI7510: All participants in the ATP who had no major protocol deviations judged to have the potential to interfere with the generation or interpretation of an immune response to MEDI7510. Here "n" represents number of participants in particular category.

End point type	Secondary

End point timeframe:

Day 1, Day 29, and End of Season 1

End point values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	947	946		
Units: Mean response				
geometric mean (confidence interval 95%)				
Day 1 (n = 944, 940)	83.39 (78.91 to 88.12)	77.96 (73.66 to 82.5)		
Day 29 (n = 926, 924)	80.05 (75.68 to 84.68)	999.03 (944.4 to 1056.81)		
End of Season 1 (n = 852, 857)	79.95 (75.27 to 84.93)	370.88 (350.9 to 391.99)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rises (GMFRs) of Serum Antibodies Against RSV by Anti-F IgG Assay

End point title	Geometric Mean Fold Rises (GMFRs) of Serum Antibodies Against RSV by Anti-F IgG Assay

End point description:

Anti-F IgG antibodies were determined by a multiplex IgG assay developed on the Meso Scale discovery platform. GMFR was calculated as: anti-log2 [mean (log2 yi)], where yi is the post dose antibody titer or T-cell count fold rise from baseline for each participant. Immunogenicity population for MEDI7510: All participants in the ATP who had no major protocol deviations judged to have the potential to interfere with the generation or interpretation of an immune response to MEDI7510. Here "n" represents number of participants in particular category.

End point type	Secondary

End point timeframe:

Day 29, and End of Season 1

End point values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	947	946		
Units: Mean fold rise				
geometric mean (confidence interval 95%)				
Day 29 (n = 926, 924)	0.96 (0.94 to 0.98)	12.78 (11.96 to 13.65)		
End of Season 1 (n = 852, 857)	0.94 (0.91 to 0.96)	4.6 (4.34 to 4.88)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who had a Post-dose Seroresponse to RSV as Measured by Anti-F IgG Assay

End point title	Percentage of Participants who had a Post-dose Seroresponse to RSV as Measured by Anti-F IgG Assay

End point description:

Anti-F IgG antibodies were determined by a multiplex IgG assay developed on the Meso Scale discovery platform. Seroresponse was defined as a >= 3-fold rise of Serum Antibodies against RSV from baseline. Immunogenicity population for MEDI7510: All participants in the ATP who had no major protocol deviations judged to have the potential to interfere with the generation or interpretation of an immune response to MEDI7510. Here "n" represents the number of participants in particular category.

End point type	Secondary

End point timeframe:

Day 29, and End of Season 1

End point values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	947	946		
Units: Percentage of Participants				
number (confidence interval 95%)				
Day 29 (n = 926, 924)	0.8 (0.3 to 1.5)	92.9 (91 to 94.4)		
End of Season 1 (n = 852, 857)	1.6 (0.9 to 2.7)	65.8 (62.5 to 69)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMTs) of Strain-Specific Hemagglutination Inhibition (HAI) Antibodies to Influenza Antigens Contained in the Seasonal Influenza Vaccine

End point title	Geometric Mean Titers (GMTs) of Strain-Specific Hemagglutination Inhibition (HAI) Antibodies to Influenza Antigens Contained in the Seasonal Influenza Vaccine

End point description:

GMT was calculated as: anti-log2 [mean(log2 xi)], where xi is the assay result for participant i. GMTs of strain-Specific HAI antibodies (H1N1, H3N2, B Brisbane, and B Phuket) were reported. Immunogenicity population for IIV: All participants in the ATP who had no major protocol deviations judged to have the potential to interfere with the generation or interpretation of an immune response to the influenza vaccine. Here "n" represents number of participants in particular category.

End point type	Secondary

End point timeframe:

Day 1 (post-dose), and Day 29 of Season 1

End point values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	464	451		
Units: Mean titer				
geometric mean (confidence interval 95%)				
H1N1, Day 1 (n = 462, 450)	54.26 (48.61 to 60.565)	55.77 (50.066 to 62.115)		
H1N1, Day 29 (n = 460, 450)	161.26 (146.241 to 177.823)	155.14 (141.356 to 170.264)		
H3N2, Day 1 (n = 462, 450)	34.81 (31.224 to 38.804)	35.99 (32.271 to 40.136)		
H3N2, Day 29 (n = 460, 450)	291.73 (260.581 to 326.604)	269.58 (241.784 to 300.569)		
B BRISBANE, Day 1 (n = 462, 450)	12.89 (11.851 to 14.025)	13.46 (12.357 to 14.672)		
B BRISBANE, Day 29 (n = 460, 450)	32.49 (29.314 to 36.007)	30.15 (27.334 to 33.257)		
B PHUKET, Day 1 (n = 462, 450)	11.42 (10.514 to 12.402)	11.81 (10.857 to 12.841)		
B PHUKET, Day 29 (n = 460, 450)	30 (27.088 to 33.219)	28.29 (25.526 to 31.348)		

Statistical analyses

No statistical analyses for this end point

Secondary: Post-dose GMFRs of Strain-Specific HAI Antibodies to Influenza Antigens Contained in the Seasonal Influenza Vaccine

End point title	Post-dose GMFRs of Strain-Specific HAI Antibodies to Influenza Antigens Contained in the Seasonal Influenza Vaccine

End point description:

GMFR was calculated as: anti-log2 [mean (log2 yi)], where yi is the post dose antibody titer or T-cell count fold rise from baseline for each participant. GMFRs of strain-Specific HAI antibodies (H1N1, H3N2, B BRISBANE, and B PHUKET) were reported. Immunogenicity population for IIV: All participants in the ATP who had no major protocol deviations judged to have the potential to interfere with the generation or interpretation of an immune response to the influenza vaccine. Here "n" represents number of participants in particular category.

End point type	Secondary

End point timeframe:

Day 29 of Season 1

End point values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	464	451		
Units: Mean fold rise				
geometric mean (confidence interval 95%)				
H1N1 (n = 460, 450)	2.97 (2.652 to 3.329)	2.78 (2.501 to 3.094)		
H3N2 (n = 460, 450)	8.42 (7.525 to 9.421)	7.49 (6.669 to 8.414)		
B BRISBANE (n = 460, 450)	2.53 (2.301 to 2.771)	2.24 (2.068 to 2.425)		
B PHUKET (n = 460, 450)	2.63 (2.419 to 2.85)	2.4 (2.217 to 2.589)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Had a Strain-specific Post-dose Seroresponse to HAI Antibody

End point title	Percentage of Participants Who Had a Strain-specific Post-dose Seroresponse to HAI Antibody

End point description:

Seroresponse was defined as a >= 4-fold rise of strain-specific HAI antibodies (H1N1, H3N2, B BRISBANE, and B PHUKET) from baseline. Immunogenicity population for IIV: All participants in the ATP who had no major protocol deviations judged to have the potential to interfere with the generation or interpretation of an immune response to the influenza vaccine. Here "n" represents number of participants in particular category.

End point type	Secondary

End point timeframe:

Day 29 of Season 1

End point values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	464	451		
Units: Percentage of Participants				
number (not applicable)				
H1N1 (n = 460, 450)	32.6	32.4		
H3N2 (n = 460, 450)	76.5	74.2		
B BRISBANE (n = 460, 450)	31.7	26.9		
B PHUKET (n = 460, 450)	33	30.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Post-dose GMTs of Serum Antibodies Against RSV by Microneutralization Assay

End point title	Post-dose GMTs of Serum Antibodies Against RSV by Microneutralization Assay

End point description:

Microneutralization assay was to be used to assess humoral immunity (HAI antibody titers) against RSV. GMT was to be calculated as: anti-log2 [mean(log2 xi)], where xi is the assay result for participant i. Per-protocol population: All participants in the ATP who were followed for qualifying symptoms for RSV until the end of the RSV surveillance period.

End point type	Secondary

End point timeframe:

Day 29, and End of Season 1

End point values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[1]	0[2]		
Units: Mean titer				
geometric mean (confidence interval 95%)	(to)	(to)		

Notes:

[1] - No participant was analyzed as the study was discontinued.

[2] - No participant was analyzed as the study was discontinued.

Statistical analyses

No statistical analyses for this end point

Secondary: Post-dose GMFRs of Serum Antibodies Against RSV by Microneutralization Assay

End point title	Post-dose GMFRs of Serum Antibodies Against RSV by

	Microneutralization Assay

End point description:

Microneutralization assay was to be used to assess humoral immunity (HAI antibody titers) against RSV. GMFR was to be calculated as: anti-log2 [mean (log2 yi)], where yi is the post dose antibody titer or T-cell count fold rise from baseline for each participant. Per-protocol population: All participants in the ATP who were followed for qualifying symptoms for RSV until the end of the RSV surveillance period.

End point type	Secondary

End point timeframe:

Day 29, and End of Season 1

End point values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[3]	0[4]		
Units: Mean titer				
geometric mean (confidence interval 95%)	(to)	(to)		

Notes:

[3] - No participant was analyzed as the study was discontinued.

[4] - No participant was analyzed as the study was discontinued.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who had a Post-dose Seroresponse to RSV by Microneutralization Assay

End point title	Percentage of Participants who had a Post-dose Seroresponse to RSV by Microneutralization Assay

End point description:

Microneutralization assay was to be used to assess humoral immunity (HAI antibody titers) against RSV. Seroresponse was defined as a >= 3-fold rise of Serum Antibodies against RSV from baseline. Per-protocol population: All participants in the ATP who were followed for qualifying symptoms for RSV until the end of the RSV surveillance period.

End point type	Secondary

End point timeframe:

Day 29, and End of Season 1

End point values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[5]	0[6]		
Units: Percentage of Participants				

Notes:

[5] - No participant was analyzed as the study was discontinued.

[6] - No participant was analyzed as the study was discontinued.

Statistical analyses

No statistical analyses for this end point

Secondary: Post-dose Geometric Mean Concentration (GMC) of Palivizumab Competitive Antibodies as Measured by a Palivizumab Competitive Enzyme Linked Immunosorbent Assay (cELISA)

End point title	Post-dose Geometric Mean Concentration (GMC) of Palivizumab Competitive Antibodies as Measured by a Palivizumab Competitive Enzyme Linked Immunosorbent Assay (cELISA)

End point description:

Palivizumab-cELISA assay was to be used to assess humoral immunity (HAI antibody titers) against RSV. GMC was to be calculated as: anti-log2 [mean(log2 xi)], where xi is the assay result for participant i. Per-protocol population: All participants in the ATP who were followed for qualifying symptoms for RSV until the end of the RSV surveillance period.

End point type	Secondary

End point timeframe:

Day 29, and End of Season 1

End point values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[7]	0[8]		
Units: Mean concentration				
geometric mean (confidence interval 95%)	(to)	(to)		

Notes:

[7] - No participant was analyzed as the study was discontinued.

[8] - No participant was analyzed as the study was discontinued.

Statistical analyses

No statistical analyses for this end point

Secondary: Post-dose GMFRs of palivizumab competitive antibodies as measured by a palivizumab cELISA

End point title	Post-dose GMFRs of palivizumab competitive antibodies as measured by a palivizumab cELISA

End point description:

Palivizumab-cELISA assay was to be used to assess humoral immunity (HAI antibody titers) against RSV. GMFR was to be calculated as: anti-log2 [mean (log2 yi)], where yi is the post dose antibody titer or T-cell count fold rise from baseline for each participant. Per-protocol population: All participants in the ATP who were followed for qualifying symptoms for RSV until the end of the RSV surveillance period.

End point type	Secondary

End point timeframe:

Day 29, and End of Season 1

End point values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[9]	0[10]		
Units: Mean Fold Rises				
geometric mean (confidence interval 95%)	(to)	(to)		

Notes:

[9] - No participant was analyzed as the study was discontinued.

[10] - No participant was analyzed as the study was discontinued.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who had a Post-dose Seroresponse to RSV as measured by palivizumab cELISA

End point title	Percentage of Participants who had a Post-dose Seroresponse to RSV as measured by palivizumab cELISA

End point description:

Palivizumab-cELISA assay was to be used to assess humoral immunity (HAI antibody titers) against RSV. Seroresponse was defined as a >= 3-fold rise of Serum Antibodies against RSV from baseline. Per-protocol population: All participants in the ATP who were followed for qualifying symptoms for RSV until the end of the RSV surveillance period.

End point type	Secondary

End point timeframe:

Day 29, and End of Season 1

End point values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[11]	0[12]		
Units: Percentage of Participants				
number (confidence interval 95%)	(to)	(to)		

Notes:

[11] - No participant was analyzed as the study was discontinued.

[12] - No participant was analyzed as the study was discontinued.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With all Solicited Symptoms

End point title	Number of Participants With all Solicited Symptoms

End point description:

Solicited symptoms: tenderness or soreness at site of injection, pain at site of injection, fatigue or tiredness, headache, generalized muscle aches, swelling at the site of injection, redness at the site of injection, fever >= 100.4 degrees Fahrenheit by any route from Day 1 to Day 7. ATP: Participants who received any dose of investigational product (IP). Participants were included in the ATP according to the IP received even if different from that to which the participant was randomized.

End point type	Secondary

End point timeframe:

Day 1 (post-dose) through Day 7

End point values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	948	946		
Units: Participants	558	606		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-Emergent Adverse Events

End point title	Number of Participants With Treatment-Emergent Adverse Events

End point description:

An adverse event (AE) was any untoward medical occurrence attributed to study drug in a participant who received IP. A serious adverse event (SAE) was an AE resulting in any of following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent events were between administration of study drug and Day 29 that were absent before treatment or that worsened relative to pre-treatment state. ATP: Participants who received any dose of IP. Participants were included in the ATP according to the IP received even if different from that to which the participant was randomized.

End point type	Secondary

End point timeframe:

Day 1 (post-dose) through Day 29

End point values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	948	946		
Units: Participants	141	146		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-Emergent Adverse Events of Special Interest (TEAESIs), Treatment-Emergent Serious Adverse Events (TESAEs) and Treatment-Emergent New Onset Chronic Disease (NOCDs)

End point title	Number of Participants With Treatment-Emergent Adverse Events of Special Interest (TEAESIs), Treatment-Emergent Serious Adverse Events (TESAEs) and Treatment-Emergent New Onset Chronic Disease (NOCDs)

End point description:

AE was any untoward medical occurrence attributed to study drug in a participant who received IP. SAE was an AE resulting in any of following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent were events between administration of study drug and approx 1 year follow up that were absent before treatment or that worsened relative to pre-treatment state. An AESI was one of scientific and medical interest specific to understanding of study product and required close monitoring and rapid communication by investigator to the sponsor. A NOCD was a newly diagnosed medical condition that is of a chronic, ongoing nature. It was observed after receiving IP and was assessed by investigator as medically significant. ATP was analyzed.

End point type	Secondary

End point timeframe:

Day 1 (post-dose) through final season 1 (follow-up period) (up to approximately 1 year)

End point values	Placebo + Inactivated Influenza Vaccine (IIV)	MEDI7510 + IIV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	948	946		
Units: Participants				
TEAESIs	0	1		
TESAEs	3	4		
NOCDs	5	4		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Day 1 (post-dose) through final season 1 (follow-up period) (up to approximately 1 year)	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups	
Reporting group title	MEDI7510+IIV
Reporting group description:	
Participants received a single IM injection of MEDI7510 in one arm and single IM injection of IIV in the contralateral arm.	
Reporting group title	Placebo + IIV
Reporting group description:	
Participants received a single IM injection of placebo (matched with MEDI7510) in one arm and single IM injection of IIV in the contralateral arm.	

Serious adverse events	MEDI7510+IIV	Placebo + IIV	
Total subjects affected by serious adverse events			
subjects affected / exposed	64 / 946 (6.77%)	57 / 948 (6.01%)	
number of deaths (all causes)	3	5	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			

subjects affected / exposed	0 / 946 (0.00%)	3 / 948 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive lobular breast carcinoma			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma metastatic			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-hodgkin's lymphoma			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer metastatic			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary thyroid cancer			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal neoplasm			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	2 / 946 (0.21%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer metastatic			

subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage i			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of head and neck			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic occlusion			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Deep vein thrombosis			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			

subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 946 (0.11%)	2 / 948 (0.21%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	1 / 946 (0.11%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Uterine prolapse			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	1 / 946 (0.11%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal septum deviation			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 946 (0.00%)	2 / 948 (0.21%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug dependence			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Craniocerebral injury			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Femur fracture			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			

subjects affected / exposed	1 / 946 (0.11%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic fracture			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			

subjects affected / exposed	2 / 946 (0.21%)	2 / 948 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	0 / 946 (0.00%)	2 / 948 (0.21%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	4 / 946 (0.42%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradyarrhythmia			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac failure acute			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac failure congestive			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	2 / 946 (0.21%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			

subjects affected / exposed	1 / 946 (0.11%)	6 / 948 (0.63%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Brain stem infarction			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 946 (0.00%)	3 / 948 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	0 / 946 (0.00%)	3 / 948 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic diathesis			

subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Glaucoma			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 946 (0.11%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis relapsing			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			

subjects affected / exposed	2 / 946 (0.21%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal perforation			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	1 / 946 (0.11%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Skin ulcer			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 946 (0.21%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
End stage renal disease			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Haematuria			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 946 (0.21%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle spasms			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	2 / 946 (0.21%)	5 / 948 (0.53%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abscess limb			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			

subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	1 / 946 (0.11%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	1 / 946 (0.11%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter infection			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected lymphocele			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			

subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	1 / 946 (0.11%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 946 (0.00%)	3 / 948 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia influenzal			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tracheobronchitis			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 946 (0.00%)	2 / 948 (0.21%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			

subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 946 (0.11%)	0 / 948 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 946 (0.00%)	1 / 948 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	MEDI7510+IIV	Placebo + IIV	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	48 / 946 (5.07%)	52 / 948 (5.49%)	
Nervous system disorders			
Headache			
subjects affected / exposed	10 / 946 (1.06%)	13 / 948 (1.37%)	
occurrences (all)	11	15	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	16 / 946 (1.69%)	11 / 948 (1.16%)	
occurrences (all)	19	13	
Injection site pain			
subjects affected / exposed	10 / 946 (1.06%)	18 / 948 (1.90%)	
occurrences (all)	28	35	
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	16 / 946 (1.69%)	10 / 948 (1.05%)	
occurrences (all)	16	10	
Viral upper respiratory tract infection			

subjects affected / exposed occurrences (all)	13 / 946 (1.37%) 13	10 / 948 (1.05%) 10	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 July 2015	The overall reason for the amendment was to: - Respiratory illness assessments, including nasal swabs and review illness workbook. - Collect and review illness workbook and 3) Provide thermometers, solicited symptom diary card, measuring tape/ruler, illness workbook, nasal swab kit and instructions; educate in use of all. - Changes were made in reference to the blinding process for IIV based on the type of presentation and whether it was a visual match to the MEDI7510 and placebo syringe or not. The on-site unblinded vaccine administrator was added to the list of individuals who had access to information that might have identified a participant's treatment allocation. - Post-dose was added to the following sentence: these individuals must not reveal randomization or treatment information to anyone or participate in or be associated with the "post-dose" evaluation of study participants.

Notes:

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.

The study was terminated due to failure to meet the primary efficacy endpoint.

Notes: