Clinical trial results:
A Phase 3 Open-label Study to Evaluate the Safety of MEDI3250 in Healthy Japanese Children age 2 years through 6 years

Summary

EudraCT number	2014-003401-15
Trial protocol	Outside EU/EEA
Global end of trial date	03 February 2015

Results information

Result version number	v1 (current)
This version publication date	01 February 2017
First version publication date	16 August 2015

Trial information

Trial identification

Sponsor protocol code	D2560C00007

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	AstraZeneca K.K.
Sponsor organisation address	3-1, Ofuka-cho, Kita-ku, Osaka, Japan, 5310076
Public contact	Research & Development, AstraZeneca K.K., 81 6 7711 4699, Takenobu.Masaoka@astrazeneca.com
Scientific contact	Research & Development, AstraZeneca K.K., 81 6 7711 4699, Takenobu.Masaoka@astrazeneca.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	08 June 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 February 2015
Global end of trial reached?	Yes
Global end of trial date	03 February 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the safety and tolerability of MEDI3250.

Protection of trial subjects:

• Study data will be stored in a computer database, maintaining confidentiality in accordance with national data legislation
• Patient data will be maintaining confidentiality in accordance with national data legislation
• For data verification purposes, authorised representatives of AstraZeneca, a regulatory authority, an IRB may require direct access to parts of the hospital or practice source records relevant to the study, including subjects' medical history
• All data computer processed by AstraZeneca will be identified by study code and enrolment code (E-code)

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 November 2014
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	Japan: 100
Worldwide total number of subjects	100
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)	0
Children (2-11 years)	100
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:

The targeted enrolled number of subject was 100 and 100 subjects were enrolled. First subject enrolled date was 01 Nov 2014 and Last subject last visit date was 03 Feb 2015.

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	100
Number of subjects completed	100

Period 1

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

Arms

Arm title	MEDI3250

Arm description: -

Arm type	Experimental
Investigational medicinal product name	MEDI3250
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal/oromucosal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

For children age 2 years through 6 years, the recommended dosage schedule for intranasal administration is 0.2 mL (0.1 mL per nostril). For children not previously vaccinated against seasonal influenza, a second dose should be given after an interval of at least 4 weeks.

Number of subjects in period 1	MEDI3250
Started	100
Completed	100

Baseline characteristics

Reporting groups

Reporting group title	MEDI3250

Reporting group description: -

Reporting group values	MEDI3250	Total	
Number of subjects	100	100	
Age categorical			
Age 2 through 6 years of age was targeted.			
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)	100	100	
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: years			
arithmetic mean	4.2		
standard deviation	± 1.4	-	
Gender categorical			
Gender was not limited, ie, both male and female were targeted.			
Units: Subjects			
Female	55	55	
Male	45	45	
Ethnicity			
Units: Subjects			
Not Hispanic or Latino	100	100	
Race			
Units: Subjects			
Asian	100	100	

Subject analysis sets

Subject analysis set title	Safety population
Subject analysis set type	Safety analysis

Subject analysis set description:

Safety Population includes all subjects who receive any amount of investigational product.

Reporting group values	Safety population		
Number of subjects	100		

Age categorical			
Age 2 through 6 years of age was targeted.			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	100		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean	4.2		
standard deviation	± 1.4		
Gender categorical			
Gender was not limited, ie, both male and female were targeted.			
Units: Subjects			
Female	55		
Male	45		
Ethnicity			
Units: Subjects			
Not Hispanic or Latino	100		
Race			
Units: Subjects			
Asian	100		

End points

End points reporting groups

Reporting group title	MEDI3250
Reporting group description: -	
Subject analysis set title	Safety population
Subject analysis set type	Safety analysis
Subject analysis set description:	
Safety Population includes all subjects who receive any amount of investigational product.	

Primary: The number of subjects with solicited symptom

End point title	The number of subjects with solicited symptom[1]
End point description:	
Solicited symptoms experienced from administration of investigational product through 14 days post vaccination by dose number (as appropriate)	
End point type	Primary
End point timeframe:	
for 14 days post vaccination	

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: This study is open-label, safety study to assess the safety and tolerability of MEDI3250, ie, no comparators/placebo, so there is no statistical analysis

End point values	MEDI3250	Safety population		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	100	100		
Units: subject	57	57		

Statistical analyses

No statistical analyses for this end point

Primary: To assess the safety and tolerability of MEDI3250

End point title	To assess the safety and tolerability of MEDI3250[2]
End point description:	
Adverse events experienced from administration of investigational product through 28 days post vaccination by dose number (as appropriate)	
End point type	Primary
End point timeframe:	
for 28 days post vaccination	

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: This study is open-label, safety study to assess the safety and tolerability of MEDI3250, ie, no comparators/placebo, so there is no statistical analysis

End point values	MEDI3250	Safety population		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	100	100		
Units: subject	42	42		

Statistical analyses

No statistical analyses for this end point

Primary: To assess the safety and tolerability of MEDI3250

End point title	To assess the safety and tolerability of MEDI3250[3]

End point description:

Treatment-emergent SAEs experienced from administration of investigational product through 28 days post vaccination by dose number (as appropriate)

End point type	Primary

End point timeframe:

For 28 days post vaccination

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: This study is open-label, safety study to assess the safety and tolerability of MEDI3250, ie, no comparators/placebo, so there is no statistical analysis

End point values	MEDI3250	Safety population		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	100	100		
Units: subject	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: To assess the safety and tolerability of MEDI3250

End point title	To assess the safety and tolerability of MEDI3250[4]

End point description:

Treatment-emergent SAEs experienced from informed consent to 28 days post last vaccination

End point type	Primary

End point timeframe:

28 days post vaccination

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: This study is open-label, safety study to assess the safety and tolerability of MEDI3250, ie, no comparators/placebo, so there is no statistical analysis

End point values	MEDI3250	Safety population		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	100	100		
Units: subject	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: For subjects with one dose, until Day 29 post-vaccination. For subjects with two doses, until Day 57 post-vaccination.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups	
Reporting group title	MEDI3250
Reporting group description: MEDI3250	

Serious adverse events	MEDI3250		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 100 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	MEDI3250		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 100 (13.00%)		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	13 / 100 (13.00%)		
occurrences (all)	13		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported