



## Clinical trial results:

### Protection induced by Live Attenuated Influenza Vaccine (LAIV or Fluenz Tetra) - applied epidemiological study

#### Summary

EudraCT number	2015-003250-41
Trial protocol	GB
Global end of trial date	13 December 2018

#### Results information

Result version number	v1 (current)
This version publication date	27 November 2019
First version publication date	27 November 2019
Summary attachment (see zip file)	Baseline Characteristics of Participants by Study Year (LAIV Protect.pdf) LAIV Protect Final Analysis (LAIV_PROTECT_FINAL ANALYSIS_050918.pdf) PCR Test Results of Samples Tested (LAIV PROTECT PCR.pdf)

#### Trial information

##### Trial identification

Sponsor protocol code	1
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##### Additional study identifiers

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

Notes:

#### Sponsors

Sponsor organisation name	Public Health England
Sponsor organisation address	61 Colindale Avenue, London, United Kingdom, NW9 5EQ
Public contact	Epidemiologist, Public Health England, 004 2083277147, chinelo.obi@phe.gov.uk
Scientific contact	Epidemiologist, Public Health England, 0044 2083277147, chinelo.obi@phe.gov.uk

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:

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**Results analysis stage**

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Analysis stage	Final
Date of interim/final analysis	07 March 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 December 2018
Global end of trial reached?	Yes
Global end of trial date	13 December 2018
Was the trial ended prematurely?	No

Notes:

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**General information about the trial**

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Main objective of the trial:

To determine efficacy of LAIV in a school age UK population

Protection of trial subjects:

Vaccine administered nasally and nasal swabs collected. No blood taken or vaccines given intramuscularly so no pain

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2015
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	24 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

Country: Number of subjects enrolled	United Kingdom: 276
Worldwide total number of subjects	276
EEA total number of subjects	276

Notes:

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**Subjects enrolled per age group**

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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)	4
Adolescents (12-17 years)	268
Adults (18-64 years)	4
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

276 children aged 10 -16 years were offered a single dose of LAIV vaccination and were given a nasal swab and asked to self-swab if they experienced flu like illness.

### Pre-assignment

Screening details:

Hypersensitivity to the active ingredients, previous systemic allergic reaction to LAIV. Previous systemic allergic reaction to an influenza vaccine (not LAIV) is a relative contra-indication which must be discussed with the CI to confirm patient suitability. Children who are clinically immunodeficient.

### Period 1

Period 1 title	Start of Season
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

### Arms

Are arms mutually exclusive?	No
<b>Arm title</b>	ARM 1

Arm description: -

Arm type	Experimental
Investigational medicinal product name	LAIV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation vapour, solution
Routes of administration	Inhalation use

Dosage and administration details:

0.2ml. 0.1ml to each nostril

<b>Arm title</b>	ARM 2
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Arm description:

The second survey where participants were followed up and self-reported any respiratory symptoms. Non of the participants were vaccinated.

Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	ARM 1	ARM 2
Started	276	243
Completed	251	243
Not completed	25	0
Lost to follow-up	25	-

**Period 2**

Period 2 title	End of Season
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

**Arms**

Are arms mutually exclusive?	No
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<b>Arm title</b>	ARM 1
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Arm description: -

Arm type	Experimental
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Investigational medicinal product name	LAIV
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Inhalation vapour, solution
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Routes of administration	Inhalation use
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Dosage and administration details:

0.2ml. 0.1ml to each nostril

<b>Arm title</b>	ARM 2
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Arm description:

The second survey where participants were followed up and self-reported any respiratory symptoms. Non of the participants were vaccinated.

Arm type	No intervention
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No investigational medicinal product assigned in this arm

<b>Number of subjects in period 2</b>	ARM 1	ARM 2
Started	276	243
Completed	251	243
Not completed	25	0
Lost to follow-up	25	-

## Baseline characteristics

### Reporting groups

Reporting group title	ARM 1
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Reporting group description: -
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Reporting group title	ARM 2
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Reporting group description:
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The second survey where participants were followed up and self-reported any respiratory symptoms. None of the participants were vaccinated.
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Reporting group values	ARM 1	ARM 2	Total
Number of subjects	276	243	276
Age categorical			
Units: Subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	272	239	272
Adults (18-64 years)	4	4	4
Gender categorical			
Units: Subjects			
Female	78	50	78
Male	198	193	198

## End points

### End points reporting groups

Reporting group title	ARM 1
Reporting group description: -	
Reporting group title	ARM 2
Reporting group description: The second survey where participants where followed up and self-reported any respiratory symptoms. Non of the participants were vaccinated.	
Reporting group title	ARM 1
Reporting group description: -	
Reporting group title	ARM 2
Reporting group description: The second survey where participants where followed up and self-reported any respiratory symptoms. Non of the participants were vaccinated.	

### Primary: PCR positive to Influenza

End point title	PCR positive to Influenza
End point description: Participants sent swab each time they experienced symptoms similar to respiratory infections. The swabs were tested for influenza	
End point type	Primary
End point timeframe: Flu Week 20 to 40	

End point values	ARM 1	ARM 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	37		
Units: PCR Positive	1	3		

### Statistical analyses

Statistical analysis title	Characteristics of participants with ILI
Statistical analysis description: Participants reporting respiratory symptoms (ILI) during the first survey were compared to those reporting in the second year of the survey to establish if there was any evidence of longevity of the flu vaccine	
Comparison groups	ARM 1 v ARM 2

Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	other
P-value	$\geq 0.05$
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.2
upper limit	1.8
Variability estimate	Standard deviation

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

within three weeks of vaccination

Adverse event reporting additional description:

NONE

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	10
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### Reporting groups

Reporting group title	All subjects
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Reporting group description: -

Serious adverse events	All subjects		
Total subjects affected by serious adverse events			
subjects affected / exposed	68 / 251 (27.09%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Respiratory, thoracic and mediastinal disorders			
Influenza like illness	Additional description: Participants reported presence of flu like symptoms during the study period		
subjects affected / exposed	68 / 251 (27.09%)		
occurrences causally related to treatment / all	0 / 154		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	All subjects		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	130 / 251 (51.79%)		
Respiratory, thoracic and mediastinal disorders			
Sore throat			
subjects affected / exposed	130 / 251 (51.79%)		
occurrences (all)	130		



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported