Clinical trial results:
Assessment of viral shedding in children previously in receipt of multiple doses of live attenuated influenza vaccine (LAIV) compared to influenza vaccine-naïve controls

Summary

EudraCT number	2017-000952-24
Trial protocol	GB
Global end of trial date	28 February 2018

Results information

Result version number	v1 (current)
This version publication date	07 February 2019
First version publication date	07 February 2019

Trial information

Trial identification

Sponsor protocol code	Flu-shed

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03104790
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Public Health England
Sponsor organisation address	Wellington House , London , United Kingdom, SE1 8UG
Public contact	Elizabeth Coates elizabeth.coates@phe.gov.uk, Public Health England Wellington House, London SE1 8UG, +44 01980612922, elizabeth.coates@phe.gov.uk
Scientific contact	Elizabeth Coates elizabeth.coates@phe.gov.uk, Public Health England Wellington House, London SE1 8UG, +44 01980612922, elizabeth.coates@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:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	28 February 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 February 2018
Global end of trial reached?	Yes
Global end of trial date	28 February 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To measure type-specific vaccine virus shedding and immunogenicity in 2017/18 and determine if there has been any change compared to previous studies in 2016/17 (conducted by this group, Eudract 2013-003592-35 and 2016-00235224) following change in the A/H1N1pdm09 vaccine virus strain amongst children with the same prior vaccine history

Protection of trial subjects:

Oral Fluids used and no blood taken or vaccines given intramuscularly so no pain

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 September 2017
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	United Kingdom: 362
Worldwide total number of subjects	362
EEA total number of subjects	362

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)	247
Adolescents (12-17 years)	115
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

362 subjects received LAIV and were asked to take three nasal swabs in the ten days after vaccination to assess vaccine virus shedding

Pre-assignment

Screening details:

Hypersensitivity to the active ingredients, gelatin or gentamicin (a possible trace residue). Previous systemic allergic reaction to LAIV. Previous 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/adolescents who are clinically immunode

Period 1

Period 1 title	PERIOD 1 (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	ARM1

Arm description:

All children

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

Number of subjects in period 1	ARM1
Started	362
Completed	362

Baseline characteristics

Reporting groups	
Reporting group title	PERIOD 1

Reporting group description: -

Reporting group values	PERIOD 1	Total	
Number of subjects	362	362	
Age categorical			
Age of children			
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)	247	247	
Adolescents (12-17 years)	115	115	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Sex of participants			
Units: Subjects			
Female	194	194	
Male	168	168	

End points

End points reporting groups

Reporting group title	ARM1
Reporting group description:	
All children	

Primary: Proportion shedding vaccine virus for H1N1

End point title	Proportion shedding vaccine virus for H1N1[1]
End point description:	
End point type	Primary
End point timeframe:	
within 10 days of 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: Descriptive analysis only

End point values	ARM1			
Subject group type	Reporting group			
Number of subjects analysed	362			
Units: Percentage	12			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
Within three weeks of vaccination	
Adverse event reporting additional description:	
NONE	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	10

Reporting groups	
Reporting group title	All subjects
Reporting group description: -	

Serious adverse events	All subjects		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 362 (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	All subjects		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 362 (0.00%)		

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Virus Shedding study only and no adverse events were solicited

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 August 2017	Addition of substudy in which additional samples (nasal, blood) will be collected allowing more detailed assessment of the immune response to LAIV and how this compares with previous years

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported