Clinical trial results:
Assessment of viral shedding week following administration of live attenuated influenza vaccine in children: FluSHED-2 study

Summary

EudraCT number	2018-002470-42
Trial protocol	GB
Global end of trial date	01 April 2019

Results information

Result version number	v1 (current)
This version publication date	16 October 2022
First version publication date	16 October 2022

Trial information

Trial identification

Sponsor protocol code	FluSHED-2

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03735147
WHO universal trial number (UTN)	-
Other trial identifiers	HRA IRAS: 250312

Notes:

Sponsors

Sponsor organisation name	Imperial College London
Sponsor organisation address	Norfolk Place, London, United Kingdom,
Public contact	Turner, IMPERIAL COLLEGE LONDON, 44 02033127754, p.turner@imperial.ac.uk
Scientific contact	Turner, IMPERIAL COLLEGE LONDON, 44 02033127754, p.turner@imperial.ac.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	30 September 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 April 2019
Global end of trial reached?	Yes
Global end of trial date	01 April 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Technical version:
To measure type-specific vaccine virus shedding in 2018/19 following LAIV administration.

Lay version:
To measure the amount and strains of flu virus in the nose of children who have had the nasal flu vaccine in the week following their vaccination.

Protection of trial subjects:

The trial involved non-invasive nasal swabbing following a routine immunisation (LAIV) to assess for timing kinetics of viral shedding. Participants were protected under GCP protocols.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 2018
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: 12
Worldwide total number of subjects	12
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)	6
Adolescents (12-17 years)	6
Adults (18-64 years)	0
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from existing paediatric services at St Mary’s Hospital, London. Recruitment was via publicity (posters, flyers), email and postal mailing.

Pre-assignment

Screening details:

Potential participants were evaluated according to eligibility criteria as outlined in the study protocol.

Period 1

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

Blinding implementation details:

n/a

Arms

Arm title	Intervention

Arm description:

Dose of LAIV given as per UK vaccine programme/national guidance

Arm type	Experimental
Investigational medicinal product name	live attenuated influenza vaccine
Investigational medicinal product code	
Other name	Fluenz Tetra
Pharmaceutical forms	Nasal/oromucosal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

Live Attenuated Intranasal Vaccine (LAIV) Quadrivalent vaccine (Fluenz-Tetra, Astra Zeneca), as provided for use by the Department of Health as part of the UK National Immunisation Schedule

DOSAGE AND ROUTE OF ADMINISTRATION
0.2 ml (administered as 0.1 ml per nostril). Immunisation will be carried out by nasal administration, as per the SmPC provided.

Number of subjects in period 1	Intervention
Started	12
Completed	12

Baseline characteristics

Reporting groups

Reporting group title	Intervention LAIV

Reporting group description: -

Reporting group values	Intervention LAIV	Total	
Number of subjects	12	12	
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)	6	6	
Adolescents (12-17 years)	6	6	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	5	5	
Male	7	7	

Subject analysis sets

Subject analysis set title	Overall cohort
Subject analysis set type	Full analysis

Subject analysis set description:
Overall cohort

Reporting group values	Overall cohort		
Number of subjects	12		
Age categorical 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)	6		
Adolescents (12-17 years)	6		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		

Gender categorical Units: Subjects			
Female Male			

End points

End points reporting groups

Reporting group title	Intervention
Reporting group description:	
Dose of LAIV given as per UK vaccine programme/national guidance	
Subject analysis set title	Overall cohort
Subject analysis set type	Full analysis
Subject analysis set description:	
Overall cohort	

Primary: Viral shedding - Day 1

End point title	Viral shedding - Day 1[1]
End point description:	
type-specific vaccine virus shedding in 2018/19 and how this varies in the 8 days following vaccination	
End point type	Primary
End point timeframe:	
Day 1 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: Minimal evidence of low level viral shedding in the minority of participants, thus no statistical analyses were feasible.

End point values	Intervention	Overall cohort		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	12	12		
Units: No. with detected viral shedding	3	3		

Attachments (see zip file)	Viral shedding data days 1-8/FluShed-2_FINAL_07102020.pdf

Statistical analyses

No statistical analyses for this end point

Primary: Viral shedding - day 2

End point title	Viral shedding - day 2[2]
End point description:	
End point type	Primary
End point timeframe:	
Day 2 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: Minimal evidence of low level viral shedding in the minority of participants, thus no statistical analyses were feasible.

End point values	Intervention	Overall cohort		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	12	12		
Units: % with detected viral shedding	3	3		

Statistical analyses

No statistical analyses for this end point

Primary: Viral shedding - Day 3

End point title	Viral shedding - Day 3[3]

End point description:

End point type	Primary

End point timeframe:

Day 3 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: Minimal evidence of low level viral shedding in the minority of participants, thus no statistical analyses were feasible.

End point values	Intervention	Overall cohort		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	12	12		
Units: % with detected viral shedding	1	1		

Statistical analyses

No statistical analyses for this end point

Primary: Viral shedding - Day 4

End point title	Viral shedding - Day 4[4]

End point description:

End point type	Primary

End point timeframe:

Day 4 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: Minimal evidence of low level viral shedding in the minority of participants, thus no statistical analyses were feasible.

End point values	Intervention	Overall cohort		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	12	12		
Units: % with detected viral shedding	3	3		

Statistical analyses

No statistical analyses for this end point

Primary: Viral shedding - Day 5

End point title	Viral shedding - Day 5[5]

End point description:

End point type	Primary

End point timeframe:

Day 5 post vaccination

Notes:

[5] - 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: Minimal evidence of low level viral shedding in the minority of participants, thus no statistical analyses were feasible.

End point values	Intervention	Overall cohort		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	12	12		
Units: % with detected viral shedding	3	3		

Statistical analyses

No statistical analyses for this end point

Primary: Viral shedding - Day 6

End point title	Viral shedding - Day 6[6]

End point description:

End point type	Primary

End point timeframe:

Day 6 post vaccination

Notes:

[6] - 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: Minimal evidence of low level viral shedding in the minority of participants, thus no statistical analyses were feasible.

End point values	Intervention	Overall cohort		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	12	12		
Units: % with detected viral shedding	3	3		

Statistical analyses

No statistical analyses for this end point

Primary: Viral shedding - Day 7

End point title	Viral shedding - Day 7[7]

End point description:

End point type	Primary

End point timeframe:

Day 7 post vaccination

Notes:

[7] - 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: Minimal evidence of low level viral shedding in the minority of participants, thus no statistical analyses were feasible.

End point values	Intervention	Overall cohort		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	12	2		
Units: % with detected viral shedding	2	12		

Statistical analyses

No statistical analyses for this end point

Primary: Viral shedding - Day 8

End point title	Viral shedding - Day 8[8]

End point description:

End point type	Primary

End point timeframe:

Day 8 post vaccination

Notes:

[8] - 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: Minimal evidence of low level viral shedding in the minority of participants, thus no statistical analyses were feasible.

End point values	Intervention	Overall cohort		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	12	12		
Units: % with detected viral shedding	2	2		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Adverse events up to Day 8 after LAIV. SAEs up to Day 28.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21

Reporting groups

Reporting group title	Intervention

Reporting group description:

Dose of LAIV given as per UK vaccine programme/national guidance

Serious adverse events	Intervention		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (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	Intervention		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 12 (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: No Adverse Events were reported in the 8 days following vaccination for any of the participants.

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.

Minimal evidence of low level viral shedding in the minority of participants, thus no statistical analyses were feasible.

Notes: