Clinical trial results:
An observational follow up study of a phase II/III, open label, randomised study of the safety, reactogenicity and immunogenicity of a single dose of meningococcal ACWY conjugate vaccine (Menveo, Glaxosmithkline or Nimenrix, Pfizer) in adolescents who were primed with Meningitec, Menjugate or Neisvac-C during preschool vaccination.

Summary

EudraCT number	2016-002381-31
Trial protocol	GB
Global end of trial date	31 August 2017

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	Quadrimeningofollowu

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02811120
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	22 January 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 August 2017
Global end of trial reached?	Yes
Global end of trial date	31 August 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Technical version:
• To estimate and compare the serogroup A, C, Y and W-specific antibody titres following ~4-5 years after vaccination with either the Glaxosmithkline or Pfizer quadrivalent meningococcal vaccines and comparison between vaccines and over time.

Lay version:
To measure how much antibody against each of the four meningitis strains included in the vaccines is still in the blood 4-5 years after vaccination with the quadrivalent vaccine and to compare this between the two groups in the original study.

Protection of trial subjects:

Fieldwork undertaken by specialist vaccine research nurses trained in venepuncture and participants offered local anaesthetic prior to venepuncture

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 2016
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: 57
Worldwide total number of subjects	57
EEA total number of subjects	57

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)	57
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

57 subjects who participated seven years earlier in a quadrivalent meningococcal conjugate vaccine trial were followed up to assess antibody persistence to each serogroup

Pre-assignment

Screening details:

Known bleeding diathesis (or any condition that may be associated with a prolonged bleeding time). Any other significant condition or circumstance which, in the opinion of the investigator, may either put the participant at risk because of participation in the study, or may influence the result of the study

Period 1

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

Blinding implementation details:

No blinding

Arms

Arm title	ARM1

Arm description:

All subjects

Arm type	Experimental
Investigational medicinal product name	Quadrivalent ACYW conjugate vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5ml

Number of subjects in period 1	ARM1
Started	57
Completed	57

Baseline characteristics

Reporting groups	
Reporting group title	PERIOD 1

Reporting group description: -

Reporting group values	PERIOD 1	Total	
Number of subjects	57	57	
Age categorical			
Age group			
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)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	57	57	
From 65-84 years	0	0	
85 years and over	0	0	
Age group	0	0	
Gender categorical			
Gender			
Units: Subjects			
Female	37	37	
Male	20	20	

End points

End points reporting groups

Reporting group title	ARM1
Reporting group description:	
All subjects	

Primary: Serogroup C

End point title	Serogroup C[1]
End point description:	
End point type	Primary
End point timeframe:	
7 years after initial 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: Followup study . descriptive analysis only

End point values	ARM1			
Subject group type	Reporting group			
Number of subjects analysed	57			
Units: Percentage protected	55			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 24 hours following blood sample	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	10

Reporting groups	
Reporting group title	ARM1
Reporting group description: -	

Serious adverse events	ARM1		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 57 (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	ARM1		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 57 (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: Followup study only involving one blood sample

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