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Be on the Team – result summary for ISRCTN

Trial Title	Evaluating the effect of immunisation with group B meningococcal vaccines on meningococcal carriage.
Short Title:	Be on the TEAM: Teenagers against Meningitis
Sponsor study Number	OVG2017/08
Sponsor:	University of Oxford
Ethics Ref:	18/SC/0055
EudraCT Number:	2017-004609-42
Chief Investigator:	Professor Sir Andrew J Pollard Professor of Paediatrics and Immunity University of Oxford, Centre for Clinical Vaccinology & Tropical Medicine (CCVTM), Churchill Hospital, Oxford OX3 7LE, United Kingdom.
Report Generated	16th February 2026

Lay Summary - Background

Sepsis and Meningitis due to Invasive Meningococcal Disease (IMD) disproportionally affects young children and adolescents. The causative bacteria, the meningococcus, is commonly carried asymptomatically in the throats of adolescents and is transmitted from person to person through respiratory secretions, only rarely causing IMD. Capsular group B meningococci (MenB) cause the majority of IMD in the UK and many regions. The vaccines licenced against MenB, 4CMenB (Bexsero) and MenB-fHbp (Trumenba) can protect individuals against IMD, but it is not known whether these vaccines reduce throat carriage and interrupt transmission to provide herd immunity to both vaccinated and unvaccinated people in the community. These vaccines are 'surrogate' MenB vaccines that work by targeting bacterial proteins common to many other meningococci so they may impact on other IMD-causing meningococci, including groups C, W, X or Y. Herd immunity is a critical factor in meningococcal vaccine policy, cost effectiveness and considerations for an adolescent MenB immunisation program.

Aim and Approach

The "Be on the TEAM" study aimed to assess whether two doses of 4CMenB or MenB-fHbp can generate herd immunity by reducing meningococcal carriage. In this school-based study, throat swabs were taken at baseline and 12-months. The carriage rates of meningococci were compared between the vaccinated groups and an unvaccinated control group.

Intent to publish

The publication is being prepared and will be linked to the ISRCTN record in due course.

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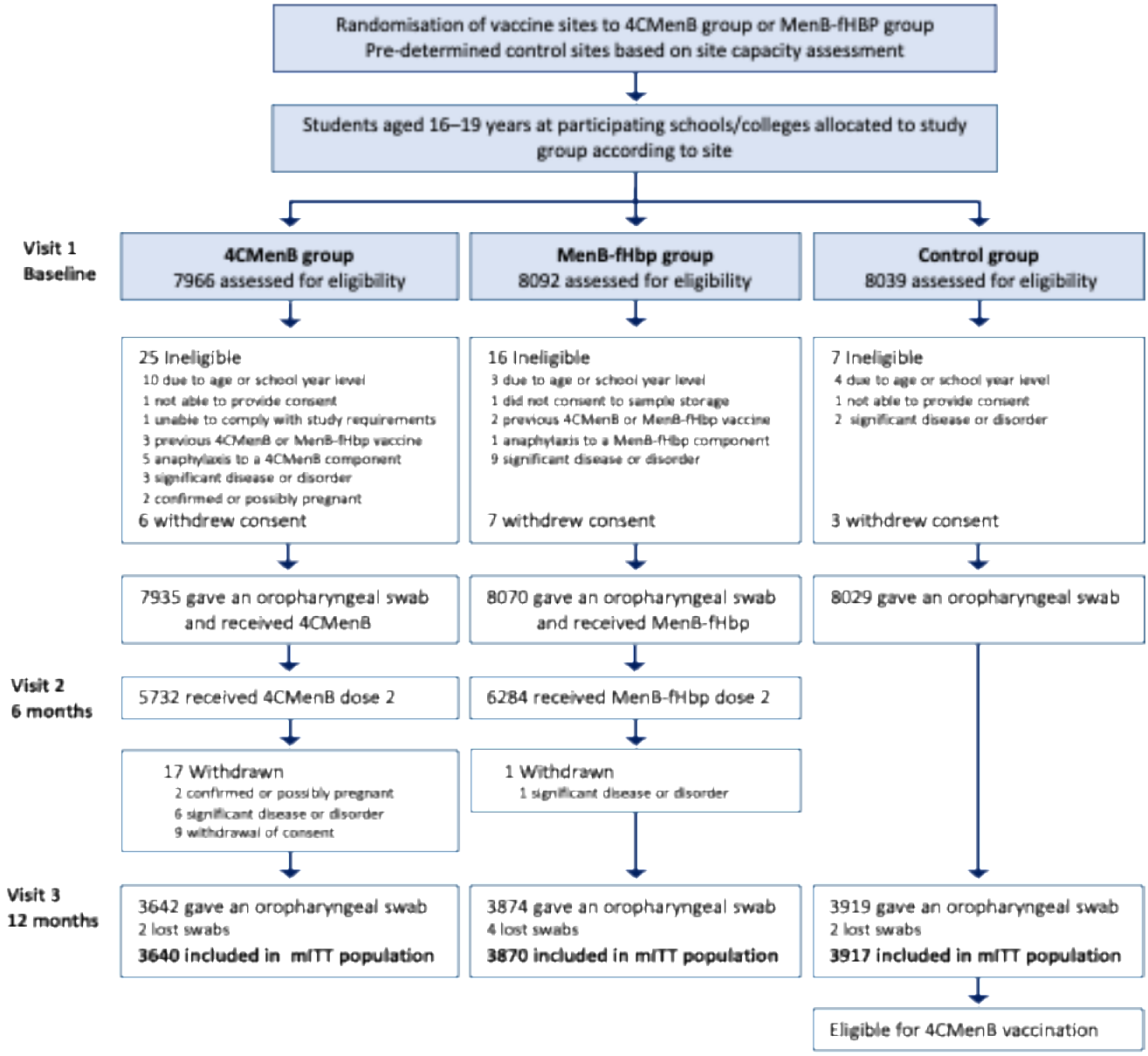
Participant Consort Diagram



mITT – modified intention to treat population: participants who gave swabs at both baseline and 12-month, regardless of vaccine receipt. Comparison between groups was done using the mITT population.

Outcome Measures

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Primary Objective To determine if immunisation with 4CMenB (Bexsero) or MenB-fHBP (Trumenba) influences the carriage of pathogenic meningococci.	Rates of carriage prevalence of any of meningococci genogroup B, C, W, Y and X before and after immunisation in both immunisation cohorts, compared with unimmunised controls	Oropharyngeal swabs taken at day 0 and 12 months (range 11-17 months).
Secondary Objectives To determine if the effect of immunisation with either 4CMenB (Bexsero) or MenB-fHBP (Trumenba) is specific to a particular *Neisseria*.	Rates of carriage prevalence of particular *Neisseria* before and after immunisation in both immunisation cohorts, compared with controls, specifically: a. genogroup B meningococci b. Hyper-invasive meningococcal strains c. All meningococcal strains d. Other Neisseria species e. Meningococci of other genogroups and capsule null meningococci f. Meningococci expressing antigens contained in 4CMenB and MenB-fHBP The difference in acquisition of carriage of all *N. meningitidis* over a 12 month period in both immunised cohorts compared to unvaccinated participants	Oropharyngeal swabs will be taken on day 0 and 12 months (range 11-17 months).

Microbiological Outcome Measures

All primary and secondary outcomes were determined by culture-confirmed *N. meningitidis*

A secondary endpoint of carriage determined by *PorA* PCR and multiplex genogroup PCR was added during the study to increase the sensitivity of *N. meningitidis* detection. This aimed to offset the effect of participant lost-to-follow up due to Covid-19 related school closures and early cessation of the study. The PCR endpoint was reported separately.

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Results

Participant Baseline Characteristics

	Control	4CMenB	MenB-fHbp
Number of participants	3917	3640	3870
Age, mean (SD)	16.34 (0.51)	16.35 (0.54)	16.34 (0.51)
Are you			
Male	1424 (36.3%)	1349 (37.0%)	1413 (36.5%)
Female	2474 (63.1%)	2261 (62.1%)	2434 (62.8%)
Non-binary	15 (0.4%)	13 (0.4%)	18 (0.5%)
What is your ethnic group?			
White	3288 (83.9%)	2897 (79.5%)	3049 (78.7%)
Asian/Asian British	314 (8.0%)	428 (11.8%)	395 (10.2%)
Black/African/Caribbean/Black British	108 (2.8%)	106 (2.9%)	182 (4.7%)
Mixed/multiple ethnic	155 (4.0%)	124 (3.4%)	174 (4.5%)
Other ethnic group	47 (1.2%)	68 (1.9%)	64 (1.7%)

MenB-fHbp Group vs Control

Carriage Category	MenB-fHbp % (n/N)	Control % (n/N)	Adj. OR	95% CI	*p* val
Primary Outcome					
Genogroups B, C, W, X, or Y	2.33 (90/3870)	3.04 (119/3917)	0.75	(0.53 - 1.07)	0.11
Secondary Outcomes					
Any *N. meningitidis*	6.36 (246/3870)	7.35 (288/3917)	0.87	(0.65 - 1.16)	0.34
Genogroup B	1.73 (67/3870)	2.09 (82/3917)	0.83	(0.55 - 1.28)	0.40
Non B, C, W, X, or Y genogroups*	3.85 (149/3870)	4.29 (168/3917)	0.93	(0.65 - 1.31)	0.69
Hyperinvasive & hyperendemic strains	2.14 (83/3870)	2.35 (92/3917)	0.85	(0.59 - 1.23)	0.38
Hyperinvasive strains	1.78 (69/3870)	1.74 (68/3917)	0.92	(0.60 -1.41)	0.71
Vaccine antigens - any *N. meningitidis*	3.74 (145/3870)	4.06 (159/3917)	0.96	(0.70 - 1.31)	0.79
Vaccine antigens - genogroup B	1.21 (47/3870)	1.12 (44/3917)	0.97	(0.57 - 1.69)	0.91
Acquisition of any *N. meningitidis*	5.39 (200/3714)	6.12 (230/3758)	0.92	(0.67 - 1.24)	0.58
N. lactamica carriage	0.93 (36/3870)	0.61 (24/3917)	1.28	(0.73 - 2.26)	0.38

% - Carriage Prevalence.

Adj OR – Adjusted Odds Ratio (cluster variable: school; adjusted for baseline carriage, meningococcal risk factors, season).

*Includes genogroups E, H, L, Z, cnl and non-groupable (NG).

Hyperinvasive strains – clonal complexes 11, 32, 41/44, 213, 269, Hyperendemic strain – clonal complex 23

Vaccine antigen – matched to vaccine antigens by the MenDeVar Index

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4CMenB vs Control

Carriage Category	4CMenB % (n/N)	Control % (n/N)	Adj. OR	95% CI	*p* val
Primary Outcome					
Genogroups B, C, W, X, or Y	3.51(128/3640)	3.04 (119/3917)	1.13	(0.80 - 1.58)	0.49
Secondary Outcomes					
Any *N. meningitidis*	8.46 (308/3640)	7.35 (288/3917)	1.08	(0.82 - 1.43)	0.56
Genogroup B	2.88 (105/3640	2.09 (82/3917)	1.44	(0.99 - 2.09)	0.06
Non B, C, W, X, or Y genogroups*	4.78 (174/3640)	4.29 (168/3917)	1.05	(0.76 - 1.45)	0.77
Hyperinvasive & hyperendemic strains	3.54 (129/3640)	2.35 (92/3917)	1.43	(0.98 - 2.10)	0.06
Hyperinvasive strains	3.24 (118/3640)	1.74 (68/3917)	1.76	(1.16 - 2.69)	0.008
Vaccine antigens - any *N. meningitidis*	1.62 (59/3640)	1.48 (58/3917)	0.98	(0.63 - 1.52)	0.94
Vaccine antigens - genogroup B	0.30 (11/3640)	0.41 (16/3917)	0.51	(0.20 - 1.30)	0.16
Acquisition of any *N. meningitidis*	7.50 (260/3465)	6.12 (230/3758)	1.24	(0.92 - 1.66)	0.15
N. lactamica carriage	0.99 (36/3640)	0.61 (24/3917)	1.26	(0.72 - 2.22)	0.42

% - Carriage Prevalence.
Adj OR – Adjusted Odds Ratio (cluster variable: school; adjusted for baseline carriage, meningococcal risk factors, season).
*Includes genogroups E, H, L, Z, cnl and non-groupables(NG).
Hyperinvasive strains – clonal complexes 11, 32, 41/44, 213, 269, Hyperendemic strain – clonal complex 23
Vaccine antigen – matched to vaccine antigens by the MenDeVar Index

4CMenB impact on N. meningitidis carriage vs control

Secondary Analysis

PCR carriage endpoint

MenB-fHbp vs Control Primary Outcome Carriage by PCR and Culture

Genogroups B, C, W, X or Y Method of Detection	MenB-fHbp n/N (%)	Control n/N (%)	Adj OR	95% CI	p-val
Culture only	2.32 (90/3870)	3.04 (119/3917)	0.75	0.53 - 1.07	0.110
PCR only	2.76 (107/3870)	3.57 (136/3917)	0.80	0.57 - 1.13	0.205
Culture or PCR	2.89 (112/3870)	3.55 (139/3917)	0.82	0.59 - 1.14	0.234

4CMenB vs Control Primary Outcome Carriage by PCR and Culture

Genogroups B, C, W, X or Y Method of Detection	4CMenB n/N (%)	Control n/N (%)	Adj OR	95% CI	p val
Culture only	3.51 (128/3640)	3.04 (119/3917)	1.13	0.80 - 1.58	0.487
PCR only	4.50 (164/3640)	3.57 (136/3917)	1.29	0.95 - 1.73	0.100
Culture or PCR	4.59 (167/3640)	3.55 (139/3917)	1.29	0.96 - 1.74	0.091

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Adverse Events

Adverse events were passively reported given that these were licensed vaccines that are currently in routine use in the UK and used according to their license. There were 19,951 doses of 4CMenB and 14,350 doses of MenB-fHbp administered in this study. No significant safety concerns have arisen for any IMPs prior to, or during this trial.

CUMULATIVE SUMMARY TABULATIONS OF ALL SAEs

Systemic Classification	4CMenB*	MenB-fHbp	Study Procedure other than IMP
Cardiovascular disorders	**1**	**2**	
Benign Cardiac Murmur			
Postural hypotension		1	
Myopericarditis	1	1	
Endocrine disorders	**1**	**3**	
Diabetes (new diagnosis)	1	1	
Diabetic ketoacidosis		1	
Hypothyroidism		1	
Eye disorders		**2**	
Visual Changes		2	
Gastrointestinal disorders	**4**	**8**	
Abdominal pain		2	
Appendicitis	2	3	
Gastroenteritis	1		
Hepatitis (Infectious)		1	
Inflammatory Bowel Disease	1	2	
Genito-urinary disorders		**1**	
Menorrhagia		1	
Immune system disorders	**1**	**2**	
Allergy	1		
Anaphylaxis		1	
Inflammatory Arthritis		1	
Infections & Infestations	**7**	**9**	**3**
Skin/Soft Tissue Infection	2	3	1
Influenza infection		2	
Tonsillitis / Pharyngitis	3	1	2
Urinary Tract Infection	1		
Urinary Tract Infection		2	
Sepsis	1		
Viral Meningitis		1	
Musculoskeletal disorders		**1**	
Cartilage Tear		1	
Neoplastic disorders		**4**	
Mass for investigation		1	
Musculoskeletal tumour		1	
Parotid carcinoma		1	
Spiradenoma		1	

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Neurological disorders	**3**	**1**	**3**
Brachial Plexitis	1		
Seizure / Epilepsy			2
Migraine / Headache	2	1	1
Psychological disorders	**2**	**2**	
Depression		1	
Eating Disorder	1	1	
Psychosis	1		
Reproductive system disorders	**1**	**2**	
Oopharitis		1	
Ovarian Cyst			
Uterine Infection	1	1	
Testicular Torsion	1		
Respiratory tract disorders	**1**	**1**	**3**
Asthma	1		2
Epistaxis		1	
Lower Respiratory Tract Infection			1
Surgical and Medical Procedures	**3**	**2**	
Elective mandibular surgery		1	
Elective Sinus Surgery		1	
Elective resection of branchial cyst	1		
Thyroidectomy	1		
Bowel Surgery	1		
Systemic Disorders	**1**		**1**
Death from intoxication/overdose	1		1

Control participants receive Bexsero at 12 months and in this table SAEs prior to vaccination as listed as "Study Procedure other than IMP". No SAEs from the control group have occurred after Bexsero.

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CUMULATIVE SUMMARY TABULATIONS OF ALL SARs

System Organ Class Preferred Term	**4CMenB**	**MenB-fHbp**	**Unexpected Reactions**
Skin and subcutaneous tissue disorders Urticaria (acute) Chronic urticaria	1	1	1
Musculoskeletal disorders Reactive arthritis Myalgia/arthralgia	1	1	1
Infections & Infestations Injection site cellulitis	2	1	
Systemic Disorders Acute febrile reaction	1		
Cardiovascular and circulatory disorders Vasovagal episode	1		