The study listed may include approved and non-approved uses, formulations or treatment regimens. The results reported in any single study may not reflect the overall results obtained on studies of a product. Before prescribing any product mentioned in this Register, healthcare professionals should consult prescribing information for the product approved in their country.

Study No.: 104702 (MenACWY-TT-012)

Title: A phase II, open (partially double-blind), randomized, controlled, primary vaccination study to assess the immunogenicity, safety and reactogenicity of one intramuscular dose of four different formulations of GlaxoSmithKline (GSK) Biologicals' new generation meningococcal serogroups A, C, W-135, Y-tetanus toxoid conjugate (MenACWY-TT) vaccine versus one subcutaneous dose of *Mencevax™ ACWY* in healthy adolescents/young adults aged 15-19 years.
Nimenrix™ - MenACWY-TT: GSK Biologicals' meningococcal serogroups A, C, W-135, Y tetanus toxoid conjugate vaccine.
Mencevax™ ACWY (MenACWY): GSK Biologicals' meningococcal serogroups A, C, W-135, Y plain polysaccharide vaccine.

Rationale: The purpose of this study was to evaluate the immunogenicity and safety of one dose of 4 different formulations of MenACWY-TT vaccine when given to healthy adolescents/young adults aged 15-19 years. MenACWY vaccine was used as control.

Phase: II

Study Period: 3 August 2005 to 27 October 2005.

Study Design: Open, (partially double-blind*), randomized, controlled, single center study with 5 parallel groups (1:1:1:1:1).
Note: eligible subjects were stratified according to age (half of the subjects aged 15 through 17 years, the other half aged 18 through 19 years) and randomized (1:1:1:1:1) within each age stratum to 1 of the 5 parallel groups.
* Double-blind regarding the MenACWY-TT formulations but open with respect to receipt of MenACWY-TT versus MenACWY.

Centers: 1 center in Denmark.

Indication: Primary immunization of healthy adolescents/young adults against meningococcal disease due to *Neisseria meningitidis* of serogroups A, C, W-135 and Y.

Treatment: The study groups were as follows:

- Form 1 Group: subjects received formulation 1 of MenACWY-TT vaccine
- Form 2 Group: subjects received formulation 2 of MenACWY-TT vaccine
- Form 3 Group: subjects received formulation 3* of MenACWY-TT vaccine
- Form 4 Group: subjects received formulation 4 of MenACWY-TT vaccine
- Control Group: subjects received MenACWY vaccine

* Approved formulation
MenACWY-TT vaccine was administered as a single dose by intramuscular injection in the deltoid region of the non-dominant arm. MenACWY vaccine was administered subcutaneously in the non-dominant upper arm.

Objectives: To evaluate the immune response induced by 4 different formulations of MenACWY-TT vaccine versus MenACWY vaccine in healthy adolescents/young adults aged 15-19 years.

Primary Outcome/Efficacy Variable:
One month after the vaccine dose, in all subjects:

- Percentage (%) of meningococcal polysaccharide A serum bactericidal assay* (SBA-MenA), meningococcal SBA-MenC, SBA-MenW-135 and SBA-MenY responders

A responder was defined** as follows:
- for initially seronegative subjects, a subject achieving a post-vaccination SBA titer of ≥ 1:32;
- for initially seropositive subjects, a subject having a ≥ 4-fold increase in SBA titer from pre to post vaccination.
* serum bactericidal assay using baby rabbit complement (rSBA) as the exogenous complement source
** *Definition modified after protocol finalization but before statistical analysis.*

Secondary Outcome/Efficacy Variable(s):
Immunogenicity:
Prior to and one month after the vaccine dose, in all subjects:

- SBA-MenA, SBA-MenC, SBA-MenW-135 and SBA-MenY titers,
- SBA-MenA, SBA-MenC, SBA-MenW-135 and SBA-MenY titers ≥ 1:8,
- SBA-MenA*, SBA-MenC, SBA-MenW-135* and SBA-MenY* titers ≥ 1:128,
- Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW-135, anti-PSY concentrations,

- Anti-PSA, anti-PSC, anti-PSW-135, anti-PSY concentrations ≥ 0.3 µg/mL,
- Anti-PSA, anti PSC, anti-PSW-135*, anti-PSY* concentrations ≥ 2 µg/mL,
- Anti-tetanus seropositivity (seroprotection) and concentration.

Safety:

- Solicited local and general symptoms occurring within 8 days (Days 0-7) after vaccination.
- Unsolicited non-serious adverse events (AEs) occurring within 31 days (Days 0-30) after vaccination.
- Serious adverse events (SAEs) occurring during the study.

** Outcome measures added after protocol finalization but before statistical analysis.*

Statistical Methods:

The analyses were performed on the Total Vaccinated Cohort and the According-To-Protocol (ATP) Cohort for immunogenicity.

- The Total Vaccinated Cohort included all vaccinated subjects for whom data were available.
- The ATP Cohort for immunogenicity included all evaluable subjects (i.e., those meeting all eligibility criteria, complying with the procedures defined in the protocol, and with no elimination criteria during the study) for whom data concerning immunogenicity were available. This included subjects for whom assay results were available for antibodies against at least one study vaccine antigen component before and one month after vaccination.

Analysis of immunogenicity

The analysis of immunogenicity was performed on the ATP Cohort for immunogenicity.
Functional anti-meningococcal serogroup activity (SBA-MenA, SBA-MenC, SBA-MenW-135, SBA-MenY) was determined by a serum bactericidal test using baby rabbit complement source (rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY).
At each time point that blood samples were available, geometric mean concentrations (GMCs) or geometric mean titers (GMTs) with 95% confidence intervals (CIs) and seropositivity or seroprotection rates with exact 95% CIs were tabulated for each antibody and for each group.

Analysis of safety

The analysis of safety was performed on the Total Vaccinated Cohort.
The percentage of subjects reporting each individual solicited local and general symptom during the 8-day (Days 0-7) follow-up period following administration of the vaccine was calculated with exact 95% CI, per group. The same calculation was performed for Grade 3 solicited local and general symptoms and for solicited general symptoms assessed as causally related to the study vaccination by the investigator. The percentage of subjects with unsolicited AEs during the 31-day (Days 0-30) follow-up period after the administration of the vaccine was tabulated according to the Medical Dictionary for Regulatory Activities (MedDRA) preferred terms. The number of subjects with SAEs during the entire study period was also tabulated according to the MedDRA preferred terms.

Study Population: Male or female subjects aged 15 through 19 years, free of obvious health problems as established by medical history and clinical examination before entering into the study, without previous vaccination against meningococcal disease of serogroup A, C, W-135 or Y and without history of meningococcal disease. Subjects had completed routine childhood vaccinations and had not received vaccination with tetanus toxoid antigen within the last 6 months. If the subject was female and of childbearing potential, she had to be abstinent or to have used contraceptive precautions for 30 days prior to vaccination; she was to have a negative pregnancy test at study entry and had to agree to continue contraceptive precautions for 2 months after the vaccination. Written informed consent was obtained from the subject prior to enrolment (for subjects below the legal age of consent, written informed consent had to be obtained from a parent or legally acceptable representative and, in addition, the subject was to sign and personally date a written informed assent).

Number of subjects	**Form 1 Group**	**Form 2 Group**	**Form 3 Group**	**Form 4 Group**	**Control Group**
Planned, N	25	25	25	25	25
Randomized, N (Total Vaccinated Cohort)	25	25	24	25	26
Completed, n (%)	25 (100)	25 (100)	24 (100)	25 (100)	26 (100)
Total Number Subjects Withdrawn, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Withdrawn due to Adverse Events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Withdrawn due to Lack of Efficacy, n (%)	Not	Not	Not	Not	Not

			applicable		applicable		applicable		applicable		applicable
Withdrawn for other reasons, n (%)			0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)
Demographics			**Form 1 Group**		**Form 2 Group**		**Form 3 Group**		**Form 4 Group**		**Control Group**
N (Total Vaccinated Cohort)			25		25		24		25		26
Females: Males			14:11		15:10		14:10		15:10		17:9
Mean Age, years (SD)			17.1 (1.29)		17.5 (1.23)		17.1 (1.25)		17.2 (1.34)		17.3 (1.00)
White/Caucasian, n (%)			24 (96.0)		24 (96.0)		23 (95.8)		25 (100)		26 (100)
Primary Efficacy Results: Vaccine response for rSBA for the different serogroups 30 days after vaccination (ATP cohort for immunogenicity)											
Group	**Pre-vaccination status**	**N**	**Vaccine Response**				**N**	**Vaccine Response**			
			n	**%**	**95% CI**			**n**	**%**	**95% CI**	
					LL	**UL**				**LL**	**UL**
		rSBA-MenA					**rSBA-MenC**				
Form 1	S-	0	0	-	0.0	-	14	14	100	76.8	100
	S+	24	18	75.0	53.3	90.2	11	8	72.7	39.0	94.0
	Total	24	18	75.0	53.3	90.2	25	22	88.0	68.8	97.5
Form 2	S-	0	0	-	0.0	-	12	12	100	73.5	100
	S+	25	18	72.0	50.6	87.9	13	10	76.9	46.2	95.0
	Total	25	18	72.0	50.6	87.9	25	22	88.0	68.8	97.5
Form 3	S-	0	0	-	0.0	-	5	5	100	47.8	100
	S+	23	20	87.0	66.4	97.2	19	18	94.7	74.0	99.9
	Total	23	20	87.0	66.4	97.2	24	23	95.8	78.9	99.9
Form 4	S-	0	0	-	0.0	-	9	9	100	66.4	100
	S+	22	17	77.3	54.6	92.2	15	14	93.3	68.1	99.8
	Total	22	17	77.3	54.6	92.2	24	23	95.8	78.9	99.9
Control	S-	1	1	100	2.5	100	11	10	90.9	58.7	99.8
	S+	22	17	77.3	54.6	92.2	13	12	92.3	64.0	99.8
	Total	23	18	78.3	56.3	92.5	24	22	91.7	73.0	99.0
		rSBA-MenW-135					**rSBA-MenY**				
Form 1	S-	3	3	100	29.2	100	2	2	100	15.8	100
	S+	22	22	100	84.6	100	22	16	72.7	49.8	89.3
	Total	25	25	100	86.3	100	24	18	75.0	53.3	90.2
Form 2	S-	5	5	100	47.8	100	5	5	100	47.8	100
	S+	20	19	95.0	75.1	99.9	20	18	90.0	68.3	98.8
	Total	25	24	96.0	79.6	99.9	25	23	92.0	74.0	99.0
Form 3	S-	4	4	100	39.8	100	2	2	100	15.8	100
	S+	19	17	89.5	66.9	98.7	22	17	77.3	54.6	92.2
	Total	23	21	91.3	72.0	98.9	24	19	79.2	57.8	92.9
Form 4	S-	3	3	100	29.2	100	2	2	100	15.8	100
	S+	22	19	86.4	65.1	97.1	23	18	78.3	56.3	92.5
	Total	25	22	88.0	68.8	97.5	25	20	80.0	59.3	93.2
Control	S-	3	3	100	29.2	100	5	5	100	47.8	100
	S+	22	21	95.5	77.2	99.9	20	17	85.0	62.1	96.8
	Total	25	24	96.0	79.6	99.9	25	22	88.0	68.8	97.5

S-= seronegative subjects (antibody titer < 1:8) prior to vaccination
S+ = seropositive subjects (antibody titer ≥ 1:8) prior to vaccination
Vaccine response defined as:
For initially seronegative subjects: post-vaccination antibody titer ≥ 1:32 at PI(D30)
For initially seropositive subjects: antibody titer at PI(D30) ≥ 4-fold the pre-vaccination antibody titer
PI(D30) = 30 days after the vaccine dose
Total = subjects either seropositive or seronegative at pre-vaccination
N = number of subjects with pre-and post-vaccination results available
n (%) = number (percentage) of subjects with a vaccine response

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable(s):

Percentage of subjects with rSBA titers ≥ 1:8 and 1:128 and GMTs (ATP Cohort for immunogenicity)

Antibody	Group	Timing	N	≥ 1:8				≥ 1:128				GMT		
				n	%	95% CI		n	%	95% CI		Value	95% CI	
						LL	UL			LL	UL		LL	UL
rSBA-MenA	Form 1	PRE	25	25	100	86.3	100	24	96.0	79.6	99.9	631.7	415.7	959.7
		PI(D30)	24	24	100	85.8	100	24	100	85.8	100	8416.8	6314.8	11218.3
	Form 2	PRE	25	25	100	86.3	100	24	96.0	79.6	99.9	749.4	511.1	1099.0
		PI(D30)	25	25	100	86.3	100	25	100	86.3	100	6299.3	4733.4	8383.3
	Form 3	PRE	23	23	100	85.2	100	23	100	85.2	100	890.7	711.9	1114.4
		PI(D30)	24	24	100	85.8	100	24	100	85.8	100	9264.0	6342.3	13531.7
	Form 4	PRE	23	23	100	85.2	100	22	95.7	78.1	99.9	993.9	663.7	1488.2
		PI(D30)	24	24	100	85.8	100	24	100	85.8	100	9632.4	7403.6	12532.2
	Control	PRE	23	22	95.7	78.1	99.9	22	95.7	78.1	99.9	680.1	381.8	1211.3
		PI(D30)	25	25	100	86.3	100	25	100	86.3	100	8283.6	6034.9	11370.3
rSBA-MenC	Form 1	PRE	25	11	44.0	24.4	65.1	8	32.0	14.9	53.5	25.9	9.7	69.0
		PI(D30)	25	25	100	86.3	100	24	96.0	79.6	99.9	3619.4	1833.2	7145.7
	Form 2	PRE	25	13	52.0	31.3	72.2	7	28.0	12.1	49.4	22.6	10.0	50.8
		PI(D30)	25	25	100	86.3	100	25	100	86.3	100	2832.8	1601.9	5009.5
	Form 3	PRE	24	19	79.2	57.8	92.9	8	33.3	15.6	55.3	47.6	23.4	97.0
		PI(D30)	24	24	100	85.8	100	24	100	85.8	100	4329.1	2404.3	7794.5
	Form 4	PRE	24	15	62.5	40.6	81.2	1	4.2	0.1	21.1	20.6	11.4	37.1
		PI(D30)	25	25	100	86.3	100	25	100	86.3	100	1943.3	1142.5	3305.5
	Control	PRE	24	13	54.2	32.8	74.4	3	12.5	2.7	32.4	21.0	10.2	43.2
		PI(D30)	25	24	96.0	79.6	99.9	24	96.0	79.6	99.9	1567.0	756.6	3245.4
rSBA-MenW-135	Form 1	PRE	25	22	88.0	68.8	97.5	13	52.0	31.3	72.2	98.2	50.9	189.5
		PI(D30)	25	25	100	86.3	100	25	100	86.3	100	5655.6	4221.2	7577.5
	Form 2	PRE	25	20	80.0	59.3	93.2	7	28.0	12.1	49.4	54.4	28.9	102.5
		PI(D30)	25	25	100	86.3	100	25	100	86.3	100	4678.8	3095.8	7071.4
	Form 3	PRE	23	19	82.6	61.2	95.0	11	47.8	26.8	69.4	83.6	38.6	180.8
		PI(D30)	24	24	100	85.8	100	24	100	85.8	100	4421.7	2938.5	6653.4
	Form 4	PRE	25	22	88.0	68.8	97.5	12	48.0	27.8	68.7	112.8	53.2	239.0
		PI(D30)	25	25	100	86.3	100	25	100	86.3	100	4947.4	3574.4	6847.8
	Control	PRE	25	22	88.0	68.8	97.5	11	44.0	24.4	65.1	78.8	42.3	146.8
		PI(D30)	25	25	100	86.3	100	25	100	86.3	100	3486.2	2446.9	4967.1
rSBA-MenY	Form 1	PRE	24	22	91.7	73.0	99.0	15	62.5	40.6	81.2	198.8	99.1	399.0
		PI(D30)	25	25	100	86.3	100	25	100	86.3	100	3890.7	2450.5	6177.3
	Form 2	PRE	25	20	80.0	59.3	93.2	14	56.0	34.9	75.6	89.0	42.6	186.0
		PI(D30)	25	25	100	86.3	100	25	100	86.3	100	3967.7	2602.3	6049.5
	Form 3	PRE	24	22	91.7	73.0	99.0	18	75.0	53.3	90.2	215.4	107.2	432.7
		PI(D30)	24	24	100	85.8	100	24	100	85.8	100	2756.0	2022.8	3754.9
	Form 4	PRE	25	23	92.0	74.0	99.0	16	64.0	42.5	82.0	187.8	90.9	388.0
		PI(D30)	25	25	100	86.3	100	25	100	86.3	100	3914.3	2441.0	6276.9
	Control	PRE	25	20	80.0	59.3	93.2	15	60.0	38.7	78.9	120.3	53.3	271.4
		PI(D30)	25	25	100	86.3	100	25	100	86.3	100	3056.4	1892.2	4936.8

N = number of subjects with available results

n (%) = number (percentage) of subjects with titer within the specified range

95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit

PRE = prior to the vaccine dose

PI(D30) = 30 days after the vaccine dose

Secondary Outcome Variable(s):

Percentage of subjects with anti-PS concentrations ≥ 0.3 µg/mL and 2.0 µg/mL and GMCs (ATP Cohort for immunogenicity)

Antibody	Group	Timing	N	≥ 0.3 μg/mL				≥ 2 μg/mL				GMC (μg/mL)		
				n	%	95% CI		n	%	95% CI		Value	95% CI	
						LL	UL			LL	UL		LL	UL
Anti-PSA	Form 1	PRE	25	18	72.0	50.6	87.9	3	12.0	2.5	31.2	0.54	0.35	0.83
		PI(D30)	25	25	100	86.3	100	25	100	86.3	100	20.23	12.10	33.82
	Form 2	PRE	25	13	52.0	31.3	72.2	2	8.0	1.0	26.0	0.40	0.24	0.66
		PI(D30)	25	25	100	86.3	100	25	100	86.3	100	16.07	9.13	28.28
	Form 3	PRE	23	14	60.9	38.5	80.3	4	17.4	5.0	38.8	0.62	0.32	1.21
		PI(D30)	24	24	100	85.8	100	24	100	85.8	100	27.26	18.50	40.16
	Form 4	PRE	25	10	40.0	21.1	61.3	3	12.0	2.5	31.2	0.36	0.20	0.65
		PI(D30)	25	25	100	86.3	100	24	96.0	79.6	99.9	20.39	12.16	34.17
	Control	PRE	23	13	56.5	34.5	76.8	1	4.3	0.1	21.9	0.36	0.24	0.55
		PI(D30)	25	25	100	86.3	100	22	88.0	68.8	97.5	12.93	7.20	23.22
Anti-PSC	Form 1	PRE	25	6	24.0	9.4	45.1	4	16.0	4.5	36.1	0.31	0.17	0.57
		PI(D30)	25	25	100	86.3	100	22	88.0	68.8	97.5	12.82	7.57	21.71
	Form 2	PRE	24	7	29.2	12.6	51.1	2	8.3	1.0	27.0	0.29	0.18	0.47
		PI(D30)	25	25	100	86.3	100	23	92.0	74.0	99.0	13.32	7.41	23.96
	Form 3	PRE	24	8	33.3	15.6	55.3	2	8.3	1.0	27.0	0.31	0.18	0.51
		PI(D30)	23	23	100	85.2	100	22	95.7	78.1	99.9	13.13	8.53	20.22
	Form 4	PRE	25	4	16.0	4.5	36.1	0	0.0	0.0	13.7	0.18	0.15	0.22
		PI(D30)	25	25	100	86.3	100	23	92.0	74.0	99.0	7.65	5.22	11.20
	Control	PRE	25	4	16.0	4.5	36.1	1	4.0	0.1	20.4	0.21	0.15	0.30
		PI(D30)	25	23	92.0	74.0	99.0	23	92.0	74.0	99.0	16.55	7.92	34.61
Anti-PSW-135	Form 1	PRE	25	5	20.0	6.8	40.7	1	4.0	0.1	20.4	0.23	0.16	0.33
		PI(D30)	25	24	96.0	79.6	99.9	19	76.0	54.9	90.6	7.00	3.63	13.49
	Form 2	PRE	25	2	8.0	1.0	26.0	0	0.0	0.0	13.7	0.17	0.14	0.20
		PI(D30)	25	25	100	86.3	100	18	72.0	50.6	87.9	5.40	2.85	10.23
	Form 3	PRE	24	6	25.0	9.8	46.7	1	4.2	0.1	21.1	0.26	0.16	0.42
		PI(D30)	24	23	95.8	78.9	99.9	15	62.5	40.6	81.2	4.45	2.09	9.48
	Form 4	PRE	25	3	12.0	2.5	31.2	1	4.0	0.1	20.4	0.20	0.14	0.27
		PI(D30)	24	24	100	85.8	100	18	75.0	53.3	90.2	7.67	3.94	14.93
	Control	PRE	25	4	16.0	4.5	36.1	2	8.0	1.0	26.0	0.22	0.15	0.34
		PI(D30)	24	24	100	85.8	100	22	91.7	73.0	99.0	11.93	6.19	22.97
Anti-PSY	Form 1	PRE	25	8	32.0	14.9	53.5	7	28.0	12.1	49.4	0.53	0.23	1.25
		PI(D30)	25	25	100	86.3	100	24	96.0	79.6	99.9	17.81	10.89	29.13
	Form 2	PRE	25	3	12.0	2.5	31.2	2	8.0	1.0	26.0	0.22	0.13	0.37
		PI(D30)	25	25	100	86.3	100	21	84.0	63.9	95.5	11.96	6.49	22.01
	Form 3	PRE	24	6	25.0	9.8	46.7	6	25.0	9.8	46.7	0.43	0.19	0.97
		PI(D30)	23	23	100	85.2	100	20	87.0	66.4	97.2	9.51	5.23	17.27
	Form 4	PRE	25	5	20.0	6.8	40.7	5	20.0	6.8	40.7	0.39	0.17	0.90
		PI(D30)	25	25	100	86.3	100	24	96.0	79.6	99.9	16.76	9.55	29.41
	Control	PRE	25	5	20.0	6.8	40.7	4	16.0	4.5	36.1	0.30	0.16	0.55
		PI(D30)	25	25	100	86.3	100	24	96.0	79.6	99.9	21.41	12.47	36.75

N = number of subjects with available results
n (%) = number (percentage) of subjects with antibody concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE = prior to the vaccine dose
PI(D30) = 30 days after the vaccine dose

Secondary Outcome Variable(s):
Percentage of subjects with anti-tetanus antibody concentrations ≥ 0.1 μg/mL and GMC (ATP Cohort for immunogenicity)

Antibody	Group	Timing	N	≥ 0.1 IU/mL				GMC		
				n	%	95% CI		value	95% CI	
						LL	UL		LL	UL
Anti-	Form 1	PRE	25	22	88.0	68.8	97.5	0.925	0.467	1.830

Tetanus		PI(D30)	25	25	100	86.3	100	16.894	11.953	23.877
	Form 2	PRE	25	23	92.0	74.0	99.0	0.752	0.367	1.540
		PI(D30)	25	25	100	86.3	100	12.160	7.761	19.053
	Form 3	PRE	24	19	79.2	57.8	92.9	0.489	0.234	1.024
		PI(D30)	24	24	100	85.8	100	12.642	8.576	18.635
	Form 4	PRE	25	23	92.0	74.0	99.0	0.780	0.436	1.397
		PI(D30)	25	25	100	86.3	100	12.990	8.497	19.858
	Control	PRE	25	21	84.0	63.9	95.5	0.666	0.347	1.277
		PI(D30)	25	23	92.0	74.0	99.0	0.679	0.371	1.244

N = number of subjects with available results
n (%) = number (percentage) of subjects with antibody concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE = prior to the vaccine dose
PI(D30) = 30 days after the vaccine dose

Secondary Outcome Variable(s):
Incidence of solicited local symptoms reported during the 8-day (Days 0-7) post-vaccination period (Total Vaccinated Cohort)

Symptom	**Intensity**	**Form 1 Group**					**Form 2 Group**				
		N	**n**	**%**	**95% CI**		**N**	**n**	**%**	**95% CI**	
					LL	**UL**				**LL**	**UL**
Pain	Any	25	12	48.0	27.8	68.7	25	10	40.0	21.1	61.3
	Grade 3	25	1	4.0	0.1	20.4	25	0	0.0	0.0	13.7
Redness	Any	25	7	28.0	12.1	49.4	25	3	12.0	2.5	31.2
	> 50 mm	25	1	4.0	0.1	20.4	25	0	0.0	0.0	13.7
Swelling	Any	25	3	12.0	2.5	31.2	25	5	20.0	6.8	40.7
	> 50 mm	25	1	4.0	0.1	20.4	25	0	0.0	0.0	13.7
		Form 3 Group					**Form 4 Group**				
Pain	Any	24	13	54.2	32.8	74.4	25	9	36.0	18.0	57.5
	Grade 3	24	0	0.0	0.0	14.2	25	1	4.0	0.1	20.4
Redness	Any	24	5	20.8	7.1	42.2	25	8	32.0	14.9	53.5
	> 50 mm	24	0	0.0	0.0	14.2	25	0	0.0	0.0	13.7
Swelling	Any	24	4	16.7	4.7	37.4	25	3	12.0	2.5	31.2
	> 50 mm	24	0	0.0	0.0	14.2	25	0	0.0	0.0	13.7

		Control Group				
Symptom	**Intensity**	**N**	**n**	**%**	**95% CI**	
					LL	**UL**
Pain	Any	26	19	73.1	52.2	88.4
	Grade 3	26	0	0.0	0.0	13.2
Redness	Any	26	5	19.2	6.6	39.4
	> 50 mm	26	0	0.0	0.0	13.2
Swelling	Any	26	3	11.5	2.4	30.2
	> 50 mm	26	0	0.0	0.0	13.2

N = number of subjects with a documented dose
n (%) = number (percentage) of subjects presenting at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval; LL = lower limit, UL = Upper Limit
Any = any solicited local symptom irrespective of intensity grade
Grade 3 pain = pain that prevented normal activity

Secondary Outcome Variable(s):
Incidence of solicited general symptoms reported during the 8-day (Days 0-7) post-vaccination period (Total Vaccinated Cohort)

Symptom	**Intensity/ relationship**	**Form 1 Group**					**Form 2 Group**				
		N	**n**	**%**	**95% CI**		**N**	**n**	**%**	**95% CI**	
					LL	**UL**				**LL**	**UL**
Fatigue	Any	25	12	48.0	27.8	68.7	25	8	32.0	14.9	53.5

	Grade 3	25	1	4.0	0.1	20.4	25	1	4.0	0.1	20.4
	Related	25	11	44.0	24.4	65.1	25	5	20.0	6.8	40.7
Fever (Axillary)	≥ 37.5°C	25	1	4.0	0.1	20.4	25	0	0.0	0.0	13.7
	> 39.5°C	25	0	0.0	0.0	13.7	25	0	0.0	0.0	13.7
	Related	25	1	4.0	0.1	20.4	25	0	0.0	0.0	13.7
Gastrointestinal	Any	25	3	12.0	2.5	31.2	25	2	8.0	1.0	26.0
	Grade 3	25	0	0.0	0.0	13.7	25	0	0.0	0.0	13.7
	Related	25	3	12.0	2.5	31.2	25	1	4.0	0.1	20.4
Headache	Any	25	9	36.0	18.0	57.5	25	8	32.0	14.9	53.5
	Grade 3	25	1	4.0	0.1	20.4	25	1	4.0	0.1	20.4
	Related	25	6	24.0	9.4	45.1	25	3	12.0	2.5	31.2
		Form 3 Group					**Form 4 Group**				
Fatigue	Any	24	6	25.0	9.8	46.7	25	9	36.0	18.0	57.5
	Grade 3	24	0	0.0	0.0	14.2	25	0	0.0	0.0	13.7
	Related	24	5	20.8	7.1	42.2	25	9	36.0	18.0	57.5
Fever (Axillary)	≥ 37.5°C	24	0	0.0	0.0	14.2	25	0	0.0	0.0	13.7
	> 39.5°C	24	0	0.0	0.0	14.2	25	0	0.0	0.0	13.7
	Related	24	0	0.0	0.0	14.2	25	0	0.0	0.0	13.7
Gastrointestinal	Any	24	4	16.7	4.7	37.4	25	2	8.0	1.0	26.0
	Grade 3	24	0	0.0	0.0	14.2	25	1	4.0	0.1	20.4
	Related	24	2	8.3	1.0	27.0	25	1	4.0	0.1	20.4
Headache	Any	24	8	33.3	15.6	55.3	25	5	20.0	6.8	40.7
	Grade 3	24	0	0.0	0.0	14.2	25	0	0.0	0.0	13.7
	Related	24	7	29.2	12.6	51.1	25	3	12.0	2.5	31.2

		Control Group				
Symptom	**Intensity/ Relationship**	**N**	**n**	**%**	**95% CI**	
					LL	**UL**
Fatigue	Any	26	10	38.5	20.2	59.4
	Grade 3	26	1	3.8	0.1	19.6
	Related	26	5	19.2	6.6	39.4
Fever (Axillary)	≥ 37.5°C	26	0	0.0	0.0	13.2
	> 39.5°C	26	0	0.0	0.0	13.2
	Related	26	0	0.0	0.0	13.2
Gastrointestinal	Any	26	5	19.2	6.6	39.4
	Grade 3	26	0	0.0	0.0	13.2
	Related	26	3	11.5	2.4	30.2
Headache	Any	26	9	34.6	17.2	55.7
	Grade 3	26	2	7.7	0.9	25.1
	Related	26	5	19.2	6.6	39.4

N = number of subjects with a documented dose
n (%) = number (percentage) of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = lower limit, UL = Upper Limit
Any = any solicited general symptom irrespective of intensity grade or relationship to vaccination
Grade 3 symptom = symptom that prevented normal activities
Related = symptom assessed by the investigator as causally related to vaccination

Safety Results: Number (%) of subjects with unsolicited adverse events during the 31-day (Days 0-30) follow-up period after vaccination (Total Vaccinated Cohort)

Most frequent adverse events- On-Therapy (occurring within Days 0-30 following vaccination)	**Form 1 Group N = 25**	**Form 2 Group N = 25**	**Form 3 Group N = 24**	**Form 4 Group N = 25**	**Control Group N = 26**
Subjects with any AE(s), n (%)	4 (16.0)	6 (24.0)	6 (25.0)	3 (12.0)	3 (11.5)
Dizziness	-	2 (8.0)	2 (8.3)	-	1 (3.8)
Nasopharyngitis	-	2 (8.0)	-	-	1 (3.8)
Pharyngolaryngeal pain	1 (4.0)	2 (8.0)	-	-	-

Genital infection fungal	-	-	1 (4.2)	-	1 (3.8)
Abdominal pain upper	1 (4.0)	-	-	-	-
Arthralgia	1 (4.0)	-	-	-	-
Cystitis	1 (4.0)	-	-	-	-
Diarrhoea	-	-	1 (4.2)	-	-
Influenza	-	-	1 (4.2)	-	-
Influenza like illness	-	1 (4.0)	-	-	-
Injection site pruritus	-	-	1 (4.2)	-	-
Malaise	-	-	-	1 (4.0)	-
Nausea	-	-	-	1 (4.0)	-
Neck pain	-	-	1 (4.2)	-	-
Pneumonia	-	-	-	-	1 (3.8)
Rash	-	-	1 (4.2)	-	-
Urticaria	-	-	-	1 (4.0)	-
-: AE absent					
Safety Results: Number (%) of subjects with serious adverse events during the entire study period (Total Vaccinated Cohort)					
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]					
All SAEs	**Form 1 Group N = 25**	**Form 2 Group N = 25**	**Form 3 Group N = 24**	**Form 4 Group N = 25**	**Control Group N = 26**
Subjects with any SAE(s), n (%) [n assessed by investigator as related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (4.0) [1]	0 (0.0) [0]
Urticaria	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (4.0) [1]	0 (0.0) [0]
Fatal SAEs	**Form 1 Group N = 25**	**Form 2 Group N = 25**	**Form 3 Group N = 24**	**Form 4 Group N = 25**	**Control Group N = 26**
Subjects with fatal SAE(s), n (%) [n assessed by investigator as related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]

Conclusion:
One month after the vaccine administration, the percentage of responders for rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibodies, respectively, were at least 72.0%, 88.0%, 88.0% and 75.0% across all the Form groups and were 78.3%, 91.7%, 96.0% and 88.0% in the Control Group.
Within 30 days following vaccination, unsolicited AEs were reported for 4 (16.0%), 6 (24.0%), 6 (25.0%), 3 (12.0%) and 3 (11.5%) subjects in Form 1, Form 2, Form 3, Form 4 and Control groups, respectively.
One SAE (urticaria) was reported in Form 4 Group; it was assessed by the investigator as potentially related to the study vaccination. No fatal SAEs were reported during this study.

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