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Immunogenicity and Safety of Booster Dose of Sputnik Light Vector Vaccine against COVID-19 in Adult Indian Subjects- A Phase III, Randomized, Open Label, Multicentre - Parallel study

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Abstract

Background and Objectives: The aim of the current study was to evaluate the immunogenicity, safety and tolerability of Sputnik-Light Vector Vaccine as heterologous booster compared to respective Homologous primary vaccine of Covaxin and Covishield as booster.

Methods: The present report comprises an interim analysis data till Day 28 which assessed the immunogenicity and safety of Sputnik-Light Vector Vaccine (as Heterologous booster) in 580 subjects. Immunogenicity of the Sputnik-Light Vector Vaccine was assessed primarily by evaluating proportion of subjects achieving ≥ 2-fold increase in virus neutralizing antibodies (VNA) at Day 28. Other immunogenicity evaluations included geometric mean titer (GMT) and geometric mean fold rise (GMFR) for SARS-CoV-2 glycoprotein specific antibody and VNA; and proportion of subjects achieving ≥2-fold increase in SARS-CoV-2 glycoprotein-specific antibodies at Day 28. The safety parameters were determined by adverse events (AEs) reported within 7 days of vaccination, and within days 8 to 28 post vaccination.

Results: Overall, 139 (55.2%) subjects of the Homologous booster group and 142 (58.0%) subjects of the Sputnik Light booster group achieved ≥ 2-fold increase in virus neutralizing antibodies at Day 28 from baseline. The proportion of difference between the groups was 2.80 [(95% CI: - 5.92:11.52). Similarly, 79 (31.5%) subjects of Homologous booster group and 99

(40.4%) subjects of Sputnik Light booster achieved ≥ 2-fold increase in SARS-CoV-2 glycoprotein specific antibodies at Day 28 from baseline and the overall proportion of difference between the groups was 8.93 [(95% CI: 0.48:17.28). Thus, Sputnik light booster met the non-inferiority criteria as the lower limit of 95% CI was ≥-10%. There was steady increase in GMT of SARS-CoV-2 glycoprotein specific antibodies and VNAs in both heterologous and homologous booster groups at Day 28. However, the GMFR (post-booster/pre-booster vaccination) was significantly higher in the Heterologous booster group for SARS-CoV-2 glycoprotein specific antibody (2.15 vs 1.86; p=0.0024) and VNA (2.31 vs 1.99; p=0.038). In Homologous booster group, of an overall 289 subjects, 49 (16.96%) subjects had reported 54 AEs. In Sputnik Light booster group, of an overall 291 subjects, 36 (12.37%) subjects had reported 43 AEs. All AEs recovered or resolved completely and no serious adverse events (SAEs) were reported in the study.

Interpretation and Conclusions: Sputnik-Light Vector Vaccine is safe and immunogenic as Heterologous booster and immunogenically non-inferior to Homologous booster of Covishield and Covaxin against SARS-CoV-2 infection.

Keywords: SARS-CoV-2; Sputnik Light Vector Vaccine; Booster dose; Virus Neutralising Antibody, Geometric Mean titre (GMT) and Geometric Mean Fold Rise (GMFR)

Introduction

Recent emergence of highly transmissible variants of SARS-CoV-2 has led to considerations for booster doses to enhance immunity and provide sustained protection from COVID-19. Emerging evidence shows that among healthcare and other frontline workers, vaccine effectiveness against COVID-19 decreases rapidly due to the combination of waning immunity and the greater exposure to virus including variants.

Data from a clinical trial show that a Pfizer's booster shot increased the immune response in trial participants, who finished primary vaccination 6 months before. It also demonstrated better virus neutralising capacity against Delta variant. [1]

On the same lines, booster dose of COVID-19 vaccines administered 6 months after primary vaccination is expected to boost immunity against the virus including neutralising capacity against the variants of concern. The US health officials has taken the decision to encourage coronavirus booster shots, after reviewing data showing that vaccine-produced immunity to milder infection decreases over time. [2] Recent findings from Israel and Qatar reported an increasing proportion of breakthrough cases among the earliest vaccinated individuals. [3,4] The transmissible delta variant [5], and the observed waning protection against symptomatic infection with time since vaccination justify the need for a booster dose in healthy adult subjects as a booster dose can dramatically increase the amount of circulating antibodies.

US FDA has already authorized booster doses of Pfizer and Moderna vaccines for entire adult population, 6 months after the primary vaccination. US FDA has also authorized use of a single booster dose of the Janssen COVID-19 Vaccine that may be administered at least 2 months after completion of the single-dose primary regimen to individuals 18 years of age and older. FDA has also allowed to "mix and match" vaccines i.e., getting a booster shot from a different drugmaker than the one that made their initial doses. [6]

The Drugs Controller General of India (DCGI) in February, 2022 granted approval to the single-shot Sputnik-Light vaccine for restricted use in emergency situation in India. [7]

According to the data from over 186,000 people aged 60-79, more than 40,000 of whom received a shot of Sputnik-Light (first dose of Sputnik V) as part of the mass-scale civil vaccination program, the infection rate between 21st and 40th day from the date of receiving the first dose was only 0.446%. At the same time, the infection rate among non-vaccinated adult population was 2.74% for a comparable period.

The interim results from Phase I/II and Phase III Trials being conducted in Russia on Sputnik- Light i.e., Component 1 (rAd serotype 26) from Gam-COVID-VAC, indicates good immunogenicity (till day 42), efficacy and safety of the same in Russian population.

In light of the above data, and results obtained from the booster vaccine studies conducted by Pfizer and Moderna, a Phase III, randomized, multicentre clinical study in parallel assignment to evaluate immunogenicity and safety of a booster dose of Sputnik-Light Vector Vaccine against COVID-19 have been proposed to be conducted in adult Indian population.

Material & Methods

Study design and setting: This is a Phase III, open label, multicentre clinical study in parallel assignment to evaluate the immunogenicity and safety of a booster dose of Sputnik-Light Vector Vaccine (Heterologous booster of recombinant adenovirus serotype 26 particles containing the SARS-CoV-2 protein S gene, in the amount of (1.0 ± 0.5) x 10^{11} particles per dose [Component 1 of Gam COVID-VAC Vaccine) in adult subjects (including those at high risk or with comorbid conditions) who were fully vaccinated against COVID-19 with either Covaxin (a whole virion inactivated coronavirus (SARS-CoV-2) or Covishield (ChAdOx1-S*[recombinant]) 5 x 10^{10} viral particles not less than 2.5 x 10^{8} infectious units) and received last dose of primary vaccination 6 - 7 months prior to screening. The study is being conducted in 580 subjects. The total expected study duration for all subjects after enrollment is 6 months.

The study protocol was reviewed and approved by Drug Controller General of India (DCGI) and Independent Ethics Committee (IEC) of clinical sites. Study was conducted according to the guidelines of Declaration of Helsinki and Principles of Good Clinical Practices. The study was conducted at 7 centres across different geographical locations in India. Each patient agreed to participate in screening procedures by signing the most recent IEC approved Informed Consent Form (ICF). Each subject was assigned a unique screening number on first cum first basis. Subjects satisfying the inclusion and none of the exclusion criteria were randomized through IWRS and the enrolment was competitive. Subjects in each primary vaccination group were randomized in 1:1 ratio to receive a booster dose with Sputnik-Light Vector Vaccine (Heterologous booster) or Homologous boosting with their respective primary vaccine.

Participants

A total of 580 subjects were enrolled in the study [289 subjects were included in Homologous booster group and 291 subjects were included in Sputnik-Light booster group]. In order to be included in the trial, subjects met all the criteria namely, male or female aged ≥ 18 years, had received primary vaccination (both doses completed) with either (a) COVAXIN (Group 1) OR (b) COVISHIELD (Group 2) where last dose of primary vaccination was taken 6-7 months prior to the screening

visit, and had passed 3 months after being asymptomatic or RT-PCR negative, if the subject was COVID-19 after primary vaccination. The subject disposition and study overview is depicted in Figure 1.

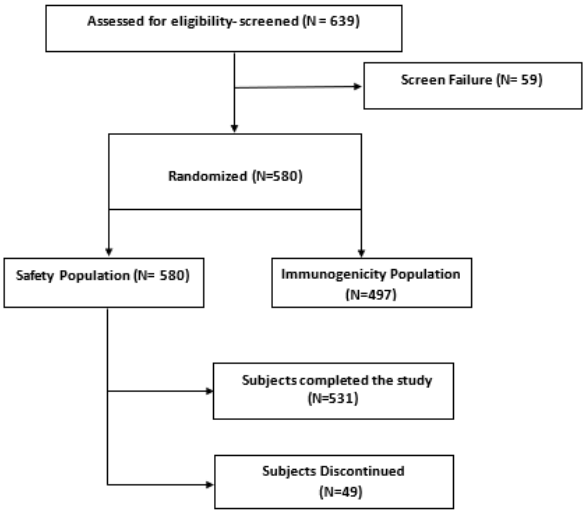

Figure 1: Diagram illustrating patient disposition and study overview

Key exclusion criteria at randomization were prior receipt of any COVID-19 vaccine in less than 6 months of duration, receiving or had received (in last 4 weeks) medication intended to prevent COVID-19 except for multi-vitamin supplements, receipt of steroids (except hormonal contraceptives) and/or immunoglobulins or other blood products within 30 days prior to enrolment, pregnancy or breast-feeding, chronic systemic infections associated with immunocompromised medical history, history of anaphylactic shock, or other life-threatening allergic reactions to drug or vaccine, neutropenia (absolute number of neutrophils less than < 1000/mm^2), agranulocytosis, severe anemia (haemoglobin < 8 g/l), immunodeficiency in the medical history within 6 months before the enrolment, and subjects with active form of a disease caused by the human immunodeficiency virus, syphilis, hepatitis B, or C were excluded from the study. Additionally, use of immunosuppressive drugs 30 days prior to and after the booster dose administration was prohibited. Participants were screened for demographics, physical and vital examination.

The present study assessed the immunogenicity of the Sputnik-Light Vector Vaccine by evaluating the proportion of subjects achieving ≥ 2-fold increase in neutralising antibodies; GMT and GMFR for SARS-CoV-2 glycoprotein specific antibody and VNA; proportion of subjects achieving ≥ 2-fold increase in SARS-CoV-2 glycoprotein-specific antibodies; lymphoproliferation (CD4+ and CD8+) and interferon gamma induction after restimulation with RBD protein; and Incidence of symptomatic COVID-19 in study subjects till end of study, severity of COVID-19, and COVID-19 outcomes (hospitalization, death, recovery without hospitalization) in study subjects. The safety of the treatment in subjects was determined by AEs reported within 7 days of vaccination, within days 8 to 28 and Post Visit 2 (Day 28 ± 3) assessments.

1.1. Laboratory assays:

Assessment of immunity after the booster dose administration was assessed by determining the humoral mediated immune response (specific antibodies titre, specific antibody test and virus-neutralising activity). Assessment of immunogenicity have been done by detection of IgG antibodies to SARS-CoV-2-S antigen by enzyme-linked immunosorbent assay (ELISA) and virus neutralising antibody assay. Cell mediated immune responses (interferon gamma concentration in T-cells) were done by flow cytometry assays.

Sample size

The sample size was calculated to compare the proportion of subjects achieving ≥ 2-fold increase in neutralising antibodies at Day 28 from baseline between

the subjects who received Sputnik- Light Vector Vaccine as booster dose and those who received Homologous booster administration with the respective primary vaccine. The proportion of subjects achieving ≥ 2-fold increase in neutralising antibodies at Day 28 was assumed as 62% in Sputnik-light booster arm and 60% in the Homologous booster arm. The estimated sample size of 260 provided 80% power at 5% two-sided level of significance to test the non-inferiority (NI) of Sputnik-light booster vaccine as compared to Homologous booster vaccines. The NI margin was 10%. Thus, approx. 290 subjects were required to be enrolled (accounting for 10% drop out) in each arm amounting to a total sample size of 580. There has been adequate representation of Covaxin and Covishield primed subjects in each arm.

1.2. Statistical Analysis:

Immunogenicity analysis set population was comprised of all subjects who received the study vaccine and for whom valid pre-dosing and at least 1 post-dosing blood sample has been received for immunogenicity. Safety analysis set population included all the subjects with documentary confirmation of receiving the study vaccine.

All immunogenicity analysis was performed on immunogenicity analysis set. Number and proportion of subjects who achieve ≥ 2-fold increase in virus neutralising antibodies have been summarized by Sputnik-light booster arm and Homologous booster arm. Subgroup analysis has been done for each primary vaccination group. 95% CI for proportion of subjects has been calculated by using Clopper-Pearson's method. The proportion between both groups has been compared by using Chi-square/ Fisher's exact test. Difference between two proportions and its 95% CI has also been presented by using Farrington-Manning method. Non-inferiority has been assessed if the lower limit of 95% confidence interval for the difference of proportion of subjects with ≥ 2-fold increase is more than or equal to 10%.

In general, the variables were summarized by using standard descriptive statistics. Continuous variables were summarized with the number (n) of non-missing observations, mean, standard deviation, median, and minimum and maximum, unless otherwise specified. For categorical data, descriptive statistics were presented with the number and percentage of subjects in the various categories of the endpoint. All the comparative analysis was considered statistically significant at 5% level of significance unless stated otherwise.

Results

The present report comprises an interim analysis data till Day 28 which assessed the immunogenicity and safety of Sputnik-Light vaccine in 580 subjects.

1.3. Patient Disposition and Demography:

Out of 640 subjects who were screened, 580 subjects were found to be eligible for the study while 60 were screen failures. All eligible subjects (580) were randomized and included in the Safety Population. All 580 subjects received the Booster Dose of vaccine on Day 1. Eleven (11) subjects had discontinued, and 569 subjects completed Visit 2 (as presented in Figure 1). The Safety population included 580 subjects, whereas the Immunogenicity population included 497 subjects (after excluding major protocol deviations).

The summary of subject demography of the safety analysis set (N = 580) is given in Table 1.

Of the 289 subjects, that were included in Homologous booster group – 184 (63.7%) subjects were male, and the rest 105 (36.3%) were female. Out of 291 subjects that were included in Sputnik-Light booster group – 172

(59.1%) subjects were male, and the rest 119 (40.9%) were female. All the subjects were of Asian ethnicity. Overall Mean ± SD age of subjects was 35.8 ± 12.70 years and 35.9 ± 13.14 years, respectively in the homologous and heterologous booster groups. Both the groups were comparable in terms of other demographic and baseline characteristics.

Table 1: Summary of Subjects demography- safety analysis Set (N = 580)

		Covaxin		Covishield		Overall	
Parameter	Statistics	Covaxin as booster (N=107)	Sputnik- Light as Booster (N=107)	Covishield as Booster (N=182)	Sputnik- Light as booster (N=184)	Homologous booster (N=289)	Sputnik- Light as booster (N=291)
Age							
	N	107	107	182	184	289	291
	Median	34.0	32.0	33.0	34.5	34.0	33.0
	Range (Min: Max)	(19.0:71.0)	(19.0:76.0)	(19.0:81.0)	(18.0:81.0)	(19.0:81.0)	(18.0:81.0)
Gender, n(%)							
	Male	60(56.1%)	57(53.3%)	124(68.1%)	115(62.5%)	184(63.7%)	172(59.1%)
	Female	47(43.9%)	50(46.7%)	58(31.9%)	69(37.5%)	105(36.3%)	119(40.9%)
Weight (kg)							
	N	107	107	182	184	289	291
	Median	64.0	63.8	65.1	66.8	65.0	65.0
	Range (Min: Max)	(45.5:84.6)	(46.0:83.0)	(40.0:92.0)	(40.0:119.1)	(40.0:92.0)	(40.0:119.1)
Height (cm)							
	N	107	107	182	184	289	291
	Median	165.0	165.0	164.7	164.0	165.0	164.0
	Range (Min: Max)	(138.0:178.0)	(134.0:178.0)	(140.0:180.0	(137.0:190.0)	(138.0:180.0)	(134.0:190.0)
BMI (kg/m^2)							
	N	107	107	182	184	289	291
	Median	23.5	23.5	24.0	24.9	23.8	24.3
	Range (Min: Max)	(18.4:30.5)	(18.6:33.4)	(15.9:35.1)	(18.0:45.1)	(15.9:35.1)	(18.0:45.1)
Race							
	Asian	107(100.0%)	107(100.0%)	182(100.0%)	184(100.0%)	289(100.0%)	291(100.0%)
[1] Percentage were calculated respective column header count as denominator.							

Immunogenicity results

Subjects who achieved ≥ 2-fold increase in viral neutralising antibodies:

Overall, 139 (55.2%) subjects of the Homologous booster group and 142 (58.0%) subjects of the Sputnik-Light booster achieved ≥ 2-fold increase in virus

neutralising antibodies at Day 28 from baseline. The overall proportion of difference between the groups was 2.80 (95% CI: -5.92:11.52) with p-value: 0.5289 (Table 2). Thus, Sputnik light booster was found to be non-inferior to the homologous boosters.

Table 2: Summary of subjects achieving ≥ 2-fold increase in Virus Neutralising Antibodies and SARS-CoV-2 glycoprotein specific antibodies from baseline

Proportion of subjects achieving ≥ 2-fold increase in Virus Neutralising Antibodies (VNA)					
Visit / Vaccine Group	Statistics	Homologous booster (N=252)	Sputnik-Light as Booster(N=245)	Proportion difference between groups (95% CI) [p value] [3]	Non-inferiority criterion met (Yes/No) #
Visit 2 (Day 28)					
Overall	Available N	252	245		
	n (%) [1]	139(55.2%)	142(58.0%)	2.80(-5.92:11.52)[0.5289]	Yes
	95% CI for proportion [2]	(48.79:61.40)	(51.51:64.21)		
Proportion of subjects achieving ≥ 2-fold increase in SARS-CoV-2 glycoprotein specific antibodies					
Overall	Available N	251	245		
	n (%) [1]	79(31.5%)	99(40.4%)	8.93(0.48:17.28)[0.0381]	Yes
	95% CI for proportion [2]	(25.78:37.61)	(34.21:46.84)		

n: Number of subjects achieving ≥2-fold increase (two-fold increase in the baseline titre value), N: Sample Size

[1] Percentages were calculated using Available N group count at each visit as denominator.

[2] 95% CI were calculated by Clopper-Pearson Method.

[3] Proportion difference was the difference of proportion of subjects with ≥2-fold increase between vaccine groups. Two-sided 95% confidence intervals for difference in proportion of subjects between groups was calculated using Farrington-Manning method. Also, p value was calculated by using z-test.

Noninferiority was assessed if the lower limit of 95% confidence interval for the difference of proportion of subjects with ≥2-fold increase is more than or equal to -10%.

GMT and GMFR for SARS-CoV-2 glycoprotein specific antibody:

The GMTs Ratio (Sputnik-Light booster/Homologous booster) was calculated as 1.00[0.82:1.21] at baseline visit and 1.16[1.03:1.31] at Visit 2 (Day 28). Non-inferiority established as the lower limit of 95% CI for GMT ratio at Day 28 was ≥ 0.67. The GMFR (Post-booster/Pre-booster vaccination) was calculated to be 1.86 for Homologous booster and 2.15 for Sputnik-Light booster group with a p-value of 0.0024. The summary of GMT and GMFR for SARS-CoV-2 glycoprotein specific antibody in immunogenicity analysis set is illustrated in Table 3.

Table 3: Summary of GMT and GMFR for SARS-CoV-2 glycoprotein specific antibody

GMTs Ratio (Sputnik Light booster/ Homologous booster) at baseline visit and at Visit 2 (Day 28)					
Visit / Vaccine Group	Statistics	Homologous booster (N=253)	Sputnik-Light as Booster (N=249)	GMTs Ratio (Sputnik-Light as Booster / Homologous booster) [95% CI] [2]	Non-inferiority criterion met (Yes/No) #
Visit 1 (Baseline) Overall					
	N	252	249		
	GMT	12266.9	12217.7	1.00[0.82:1.21]	NA
	95 % CI of GMT	(10702.57:14059.92)	(10616.72:14060.08)		
Visit 2 (Day 28) Overall					
	N	252	245		
	GMT	22984.4	26717.7	1.16[1.03:1.31]	Yes
	95 % CI of GMT	(21051.37:25095.03)	(24628.78:28983.83)		
	GMFR (Post-booster/Pre-booster vaccination) [p-value] [4]	1.86	2.15[0.0024]		

[1] 95% CI of GMT and GSD were calculated by taking the log transformation (base 10) of concentration.

[2] 95% CI of GMT ratio were calculated using Wald method on the log transformed (base 10) concentration.

[3] p-value were calculated using t-test between two arms.

[4] p-value were calculated for GMFR using two sample t-test.

*ANCOVA was performed keeping post-booster log transformed (base 10) titre as outcome, group as independent variable and baseline log transformed (base 10) titre as covariate.

**Least Square GMT obtained from ANCOVA Model.

GMT = Geometric Mean Titre; GSD= Geometric Mean Standard Deviation; GMFR= Geometric Mean Fold Rise; NA: Not Applicable

Noninferiority was established if the lower limit of 95% CI for ratio will not be less than 0.67.

GMT and GMFR for SARS-CoV-2 Virus Neutralising Antibody

The GMTs Ratio (Sputnik-Light booster/ Homologous booster) was calculated as 1.09[0.83:1.43] at baseline visit and 1.21[1.00:1.45; p= 0.0484] at Visit 2 (Day 28). Non-inferiority established as the lower limit of 95% CI for GMT ratio at Day 28 was ≥ 0.67. The GMFR (Post-booster/Pre-booster vaccination) was calculated to be 1.99 for Homologous booster and 2.31 for Sputnik-Light booster group with a p-value of 0.0380. Summary of GMT and GMFR for SARS-CoV-2 virus neutralising antibody in immunogenicity analysis set is given in Table 4.

Table 4: Summary of GMT and GMFR for SARS-CoV-2 Virus Neutralising Antibody

GMTs Ratio (Sputnik Light booster/ Homologous booster) at baseline visit and at Visit 2 (Day 28)					
Visit / Vaccine Group	Statistics	Homologous booster (N=252)	Sputnik-Light as Booster(N=245)	GMTs Ratio (Sputnik-Light as Booster / Homologous booster) [95% CI] [2]	Non-inferiority criterion met (Yes/No) #
Visit 1 (Baseline) Overall					
	N	252	245		
	GMT	100.2	109.2	1.09[0.83:1.43]	NA
	95 % CI of GMT	(82.54:121.74)	(90.13:132.33)		
Visit 2 (Day 28) Overall					
	N	252	245		
	GMT	203.8	246.0	1.21[1.00:1.45]	Yes
	95 % CI of GMT	(177.19:234.45)	(217.27:278.46)		
	GMFR (Post-booster/Pre-booster vaccination)) [p-value] [4]	1.99	2.31[0.0380]		

[1] 95% CI of GMT and GSD were calculated by taking the log transformation (base 10) of concentration.

[2] 95% CI of GMT ratio were calculated using Wald method on the log transformed (base 10) concentration.

[3] p-value were calculated using t-test between two arms.

[4] p-value were calculated for GMFR using two sample t-test.

GMT = Geometric Mean Titre; GMFR= Geometric Mean Fold Rise; NA: Not Applicable

Noninferiority was established if the lower limit of 95% CI for ratio will not be less than 0.67.

Subjects who achieved ≥ 2-fold increase in SARS-CoV-2 glycoprotein specific antibodies:

Overall, 79 (31.5%) subjects of Homologous booster group and 99 (40.4%) subjects of Sputnik Light booster achieved ≥ 2-fold increase in SARS-CoV-2 glycoprotein specific antibodies at Day 28 from baseline and the overall proportion of difference between the groups was 8.93 (95% CI: 0.48:17.28) with p-value: 0.0381. Thus, Sputnik light booster was found to be non-inferior to the homologous boosters. (Table 2).

1.4. Safety:

Within 7 days of vaccination, 7.8% of subjects of the Homologous booster group and 5.5% subjects of the Sputnik-Light booster group reported AEs while during days 8 - 28, 0.5% of subjects of the Homologous booster group and 0.9% of subjects of the Sputnik-Light booster group reported AEs. In Homologous booster group, of an overall 289 subjects, 49 (16.96%) subjects had reported 54 AEs. In Sputnik-Light booster group, of an overall 291 subjects, 36 (12.37%) subjects had reported 43 AEs. The most frequent AEs reported in Homologous booster group were injection site pain (20 events), headache (8 events), fatigue (5 events) and pyrexia (5 events). The most frequent AEs reported in Sputnik-Light booster group were injection site pain (11 events), pyrexia (11 events), asthenia (4 events), and back pain (3

events). Most of these AEs were mild in nature and all of them recovered uneventfully. None of the subjects reported SAEs.

Discussion

In India, the current state of heterologous boosters is still in development. The national drug regulator granted CMC Vellore permission to undertake homologous and heterologous booster dosage trials last year. Currently, CMC Vellore is striving to gather sufficient data to be able to submit before the CDSCO. The information will then be provided to National Immunization Technical Advisory Group (NTAGI), which is currently reviewing the scientific evidence in support of advising mix-and-match booster dose against Covid-19 to the health ministry.

Data for the current Phase III study obtained till Day 28, suggests that Sputnik-Light vaccine as Heterologous booster is non-inferior to those receiving Homologous boosters with their respective primary vaccine of Covaxin or Covishield in terms of proportions of subjects with ≥2-fold increase in virus neutralizing antibodies. The lower limit of 95% confidence interval for the difference of proportion of subjects with ≥2- fold increase was more than -10%. There was a stable increase in GMT and GMFR values of both glycoprotein specific antibody and SARS-CoV-2 virus neutralising antibody. Most of these AEs were mild in nature and all of them recovered uneventfully. None of the subjects reported SAEs.

A study in Argentina on heterogeneous regimens combining Sputnik Light and vaccines produced by AstraZeneca, Sinopharm, Moderna and Cansino has demonstrated that each “vaccine cocktail” combination with Sputnik Light provided higher antibody titer on 14th day after administering the second dose as compared to original homogenous (same vaccine as first and second dose) regimens of each of the vaccines. [8]

This interim analysis results also showed that the use of a mix-and-match strategy demonstrate a comparable vaccine efficacy with homologous boosters.

Added value of this study

In the present interim analysis, a comprehensive analysis of the immunogenicity and safety of homologous and the sputnik light vector vaccine as heterologous booster in real world Indian clinical setting was reported. The interim analysis report suggests that the overall proportion of difference in ≥2-fold increase in VNA were non-inferior (p-value: 0.5289) between the heterologous and homologous booster groups. Also, cell-mediated immune response measured by CD4/CD8 lymphoproliferation (the Mean (SD) CD8 increased from 0.3(0.22) to 1.2(1.68) by Day 28) and response of interferon-gamma after RBD stimulation by Day 28 was comparable between the two groups.

Limitation of the study

Neutralisation titres against the emerging delta and omicron variants could not be assessed in the present study.

Conclusion

The interim analysis results indicate that Sputnik-Light Vector Vaccine is safe and immunogenic as Heterologous booster and is immunogenically non-inferior to Homologous booster against SARS-CoV-2 infection.

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