CAHIERS MAGELLANES-NS
Volume 06 Issue 2
2024

ISSN:1624-1940
DOI 10.6084/m9.figshare.261151
http://magellanes.com/

AN OBSERVATIONAL STUDY TO EVALUATE THE POSTVACCINATION SYMPTOMS (COVAXIN) IN GENERAL POPULATION MORE THAN 18 YEARS OF AGE.

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Abstract
Background- When a patient receives the vaccine, their immune system is triggered to produce antibodies, preparing them to battle any coronavirus infection
Objectives- To Assess the post Vaccination symptoms of Covaxine in adult population (more than 18 Year). To evaluate the quality of life after completion of both the doses as per WHOQOL Questionnaire.
Methods- A Phase III, Randomized, Open blind, A Pilot study to evaluate the safety of COVAXIN in Post vaccination of adults s <60 Years of group study Patients who fulfill protocol specific Inclusion/Exclusion criteria will be included in the study after informed consent has been obtained. The design and focus of the study are dependent on the current COVID-19 pandemic, requiring identification of participant candidates at high risk of SARS-CoV-2 infection. The Sponsor may adjust the size of the study or duration of follow-up based on the blinded review of the total number of cases of COVID-19 accrued during the study, in addition to estimated percentages of study participants with immunologic evidence of SARS-CoV-2 infection at baseline. A total of 100 subjects with equal randomization between treatment groups will be targeted for the current study.
Results- Analysis of 1st dose showed a total no. of 100 subjects completed study. Out of which, 12% subject having Fever in 5% are female & 7% are Male. 88% not having Fever, in 23% are female & 65% are male subject. Out of which, 2% subject having Cough in 1% are female &1% are male and 98% not having Cough in 27 % are female & 71% are male, 1% subject having Breathlessness in 1% are male and 99% not having Breathlessness in 28 % are female & 71 % are male. 48% suggest good quality of life post vaccination. 38% had negative feelings very often like depression, anxiety post vaccination
Conclusion- We found that most of the participants reported fever, pain at the site of the injection, body ache, and headache, and they are more common in those after the second dose of the vaccines. A follow-up study on population is warranted to evaluate the safety of the vaccine on the control and prevention of SARS-CoV-2 infection as well as the long-term side effects.

Keywords- AEFI, COVAXIN, Cough, Fever, WHOQOL.

INTRODUCTION

The coronavirus disease 19 (COVID-19), a highly transmissible and fatal virus infection (SARS-CoV-2), that initially surfaced in Wuhan, China, could be caused by the severe acute respiratory syndrome coronavirus, China, and has since spread throughout the world. Because SARS-CoV-2 is phylogenetically related to SARS-like (SARS-like) bat viruses, bats may be the major reservoir. The Chinese government initially identified nCoV as the cause of an ongoing outbreak of lower tract sickness known as novel Coronavirus pneumonia (NCP) in 2019. The World Health Organization later suggested COVID-19 as a replacement name. In the meanwhile, the International Committee on Virus Taxonomy has designated 2019-nCoV as a new virus SARS-CoV-2.[1]

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Respiratory failure, acute respiratory distress syndrome (ARDS), sepsis and septic shock, and thromboembolism are only a few of the complications that can lead to death. People over 60, as well as those with underlying medical conditions including high blood pressure, heart and lung disease, diabetes, obesity, or cancer, are more likely to develop major illnesses.

The Serum Institute of India, the world's largest vaccine maker, manufactures the Oxford-AstraZeneca vaccine in India. It promises to be capable of producing over 60 million doses every month. A weakened chimp variant of a common cold virus is used to create the vaccine (known as an adenovirus). Despite the fact that it cannot cause illness, it has been designed to look like coronavirus. When a patient receives the vaccine, their immune system is triggered to produce antibodies, preparing them to battle any coronavirus infection.[2]

The vaccination is administered in two doses, four to twelve weeks apart. It can be kept at temperatures between 2 and 8 degrees Celsius and supplied in existing health-care facilities such as doctors' offices.

Bharat Biotech collaborated with the Indian Council of Medical Research (ICMR) - National Institute of Virology to create COVAXIN, India's indigenous COVID-19 vaccine (NIV). The vaccine was approved for Phase I and II Human Clinical Trials by the DCGI in July 2020. ICMR also proposed a Phase III multicentric clinical trial (one site at ESI Hospital in Faridabad) to evaluate the protection, safety, and immunogenicity of BBV152B, a whole-virion inactivated SARS-CoV-2 vaccine.[3]

As a result of the Corona Virus pandemic, the world changed tremendously. It had a negative impact on everyone's mental, physical, and financial health. The purpose of this study is to use the WHOQOL questionnaire to measure a person's quality of life after getting both doses of Covid-19 vaccination.

METHOD AND MATERIAL

A Phase III, Randomized, Open blind, A Pilot study to evaluate the safety of COVAXIN in Post vaccination of adults s <60 Years of group study Patients who fulfill protocol specific Inclusion/Exclusion criteria will be included in the study after informed consent has been obtained. The design and focus of the study are dependent on the current COVID-19 pandemic, requiring identification of participant candidates at high risk of SARS-CoV-2 infection. The Sponsor may adjust the size of the study or duration of follow-up based on the blinded review of the total number of cases of COVID-19 accrued during the study, in addition to estimated percentages of study participants with immunologic evidence of SARS-CoV-2 infection at baseline. A total of 100 subjects with equal randomization between treatment groups will be targeted for the current study.

Safety Assessments, Physical, Clinical examination, Vital signs and Adverse Event monitoring will be done on all scheduled hospital visits. Total duration of the study would be 6 months.

Inclusion Criteria

1. Patients of both sexes aged from >18 years to 60 years old.
2. Willing and able to provide written informed consent prior to performing study procedures by the subject or legal guardian willing and able to provide written informed consent prior to performing study procedures.
3. Agrees not to participate in another clinical trial at any time during the study period.
4. Agrees not to take any COVID-19 licensed vaccination for the entire duration of the study.
5. Agrees to remain in the study area for the entire duration of the study.

- **Exclusion Criteria**

1. Patients aged <18 and >60 years.
2. Subject or Authorized Representative is unable to provide informed consent.
3. History of any other COVID-19 investigational or licensed vaccination.
4. Known history of SARS-CoV-2 infection, as declared by the subject.
5. For women, positive urine pregnancy test before the first dose of vaccination, or any time during the study period.
6. Resident of COVID-19 infection in same household.

ISSN:1624-1940
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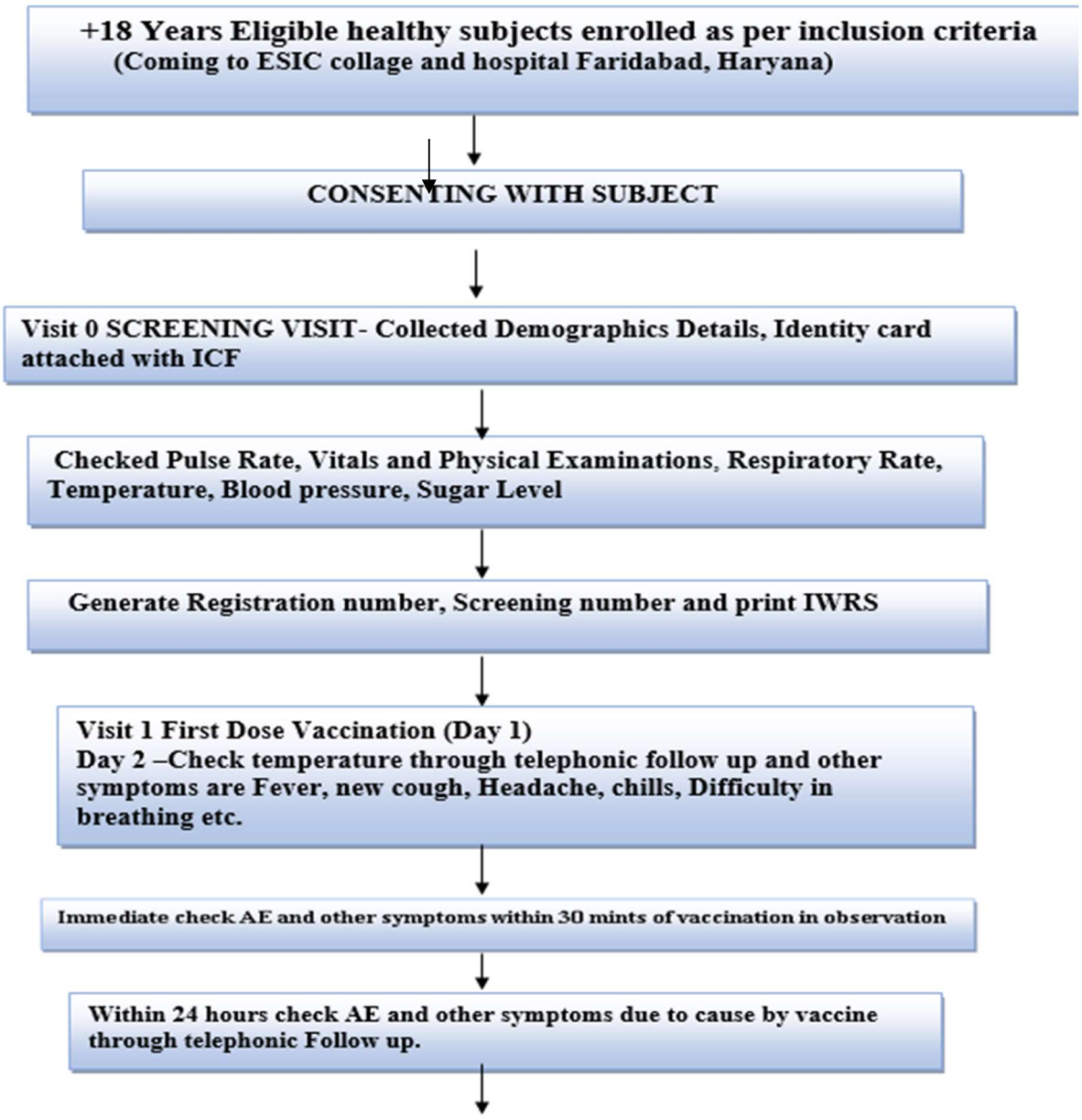
7. Known case of HIV, hepatitis B, or hepatitis C infection.
8. Receipt of immunoglobulin or other blood products within the three months before vaccination in this study.

Methodology



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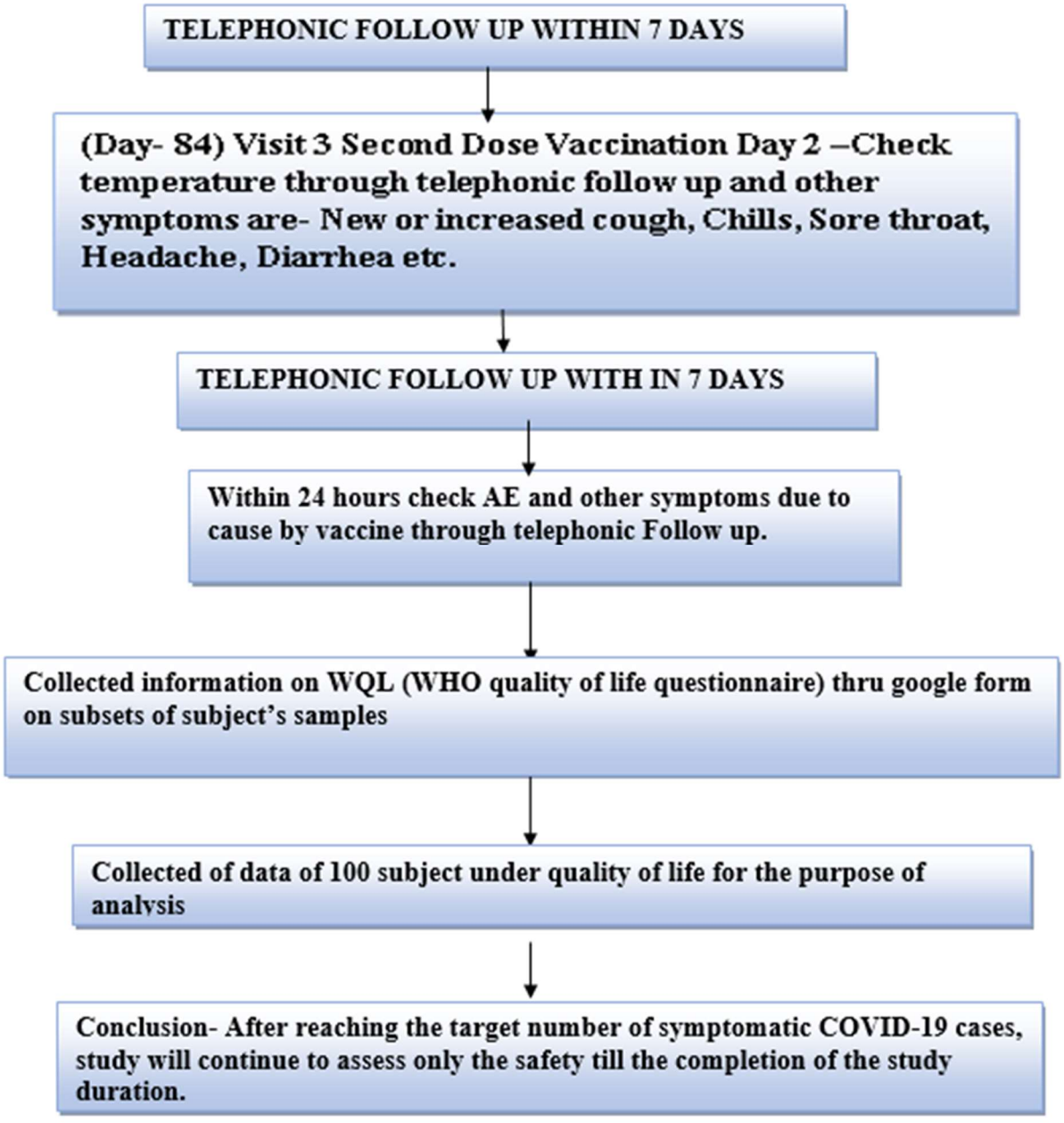

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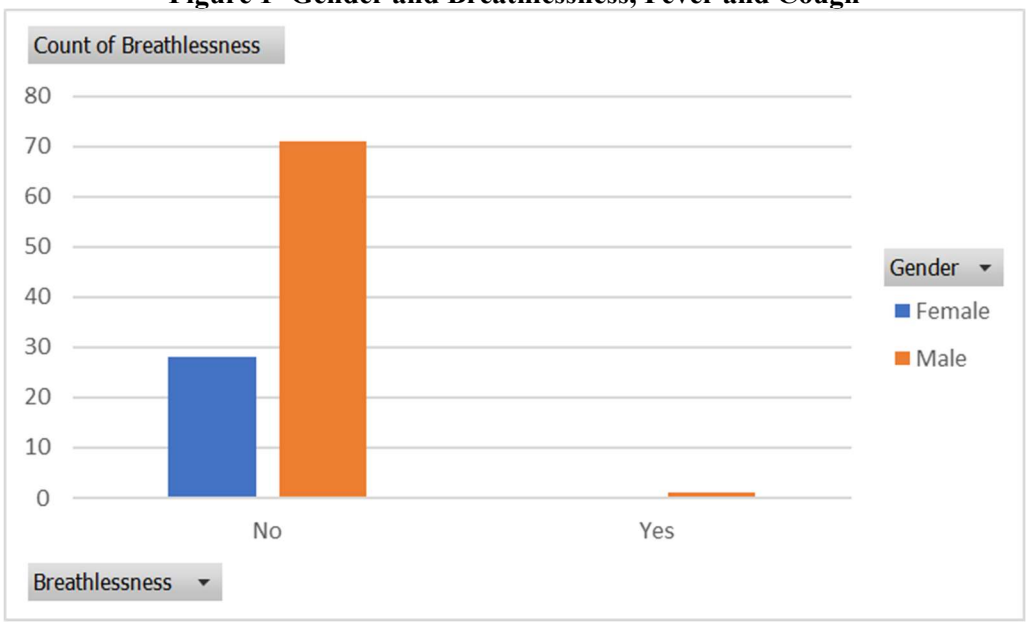
RESULTS

Data Analysis for 1st Dose of Covaxin Trial

Figure 1- Gender and Breathlessness, Fever and Cough



A total no. of 100 subjects completed study. Out of which, 12% subject having Fever in 5% are female & 7% are Male. 88% not having Fever, in 23% are female & 65% are male subject. Out of which, 2% subject having Cough in 1% are female &1% are male and 98% not having Cough in 27 % are female & 71% are male, 1% subject having Breathlessness in 1% are male and 99% not having Breathlessness in 28 % are female & 71 % are male.

Figure 2- Loss of Smell among Gender

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DOI 10.6084/m9.figshare.261151
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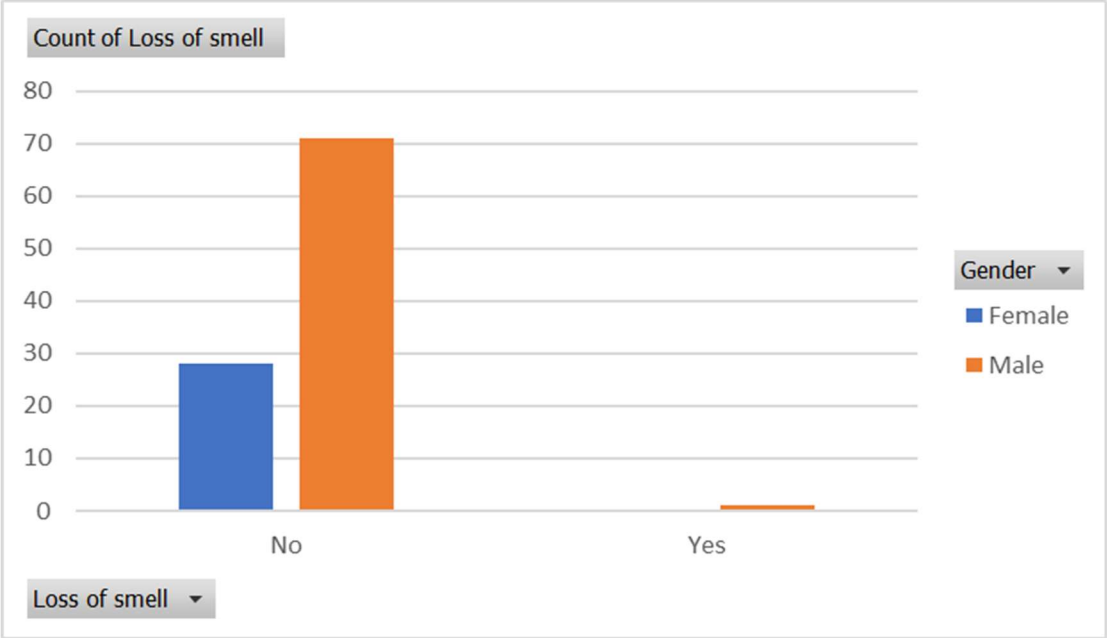
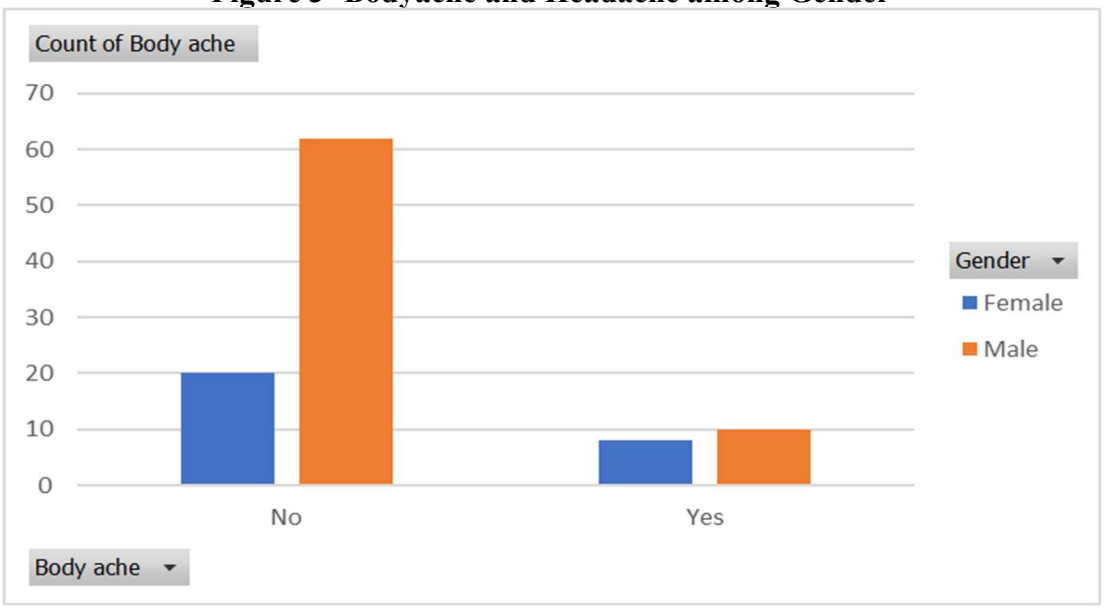


A total no. of 100 subjects completed study. Out of which, 1% subject having Loss of smell in are male and 99% not having loss of smell in 28% female & 71 are male.

Figure 3- Bodyache and Headache among Gender



A total no. of 100 subjects completed study. Out of which, 18% subject Body ache in 8% are female &10% are male and 82% not having loss of smell in 20% are female & 62% are male subject. 8% subject having Headache in 22% are female & 70% are male and 92% not having Headache in 6% are female 2% are male subject.

Figure 4- Nausea and Gender

ISSN:1624-1940
DOI 10.6084/m9.figshare.261151
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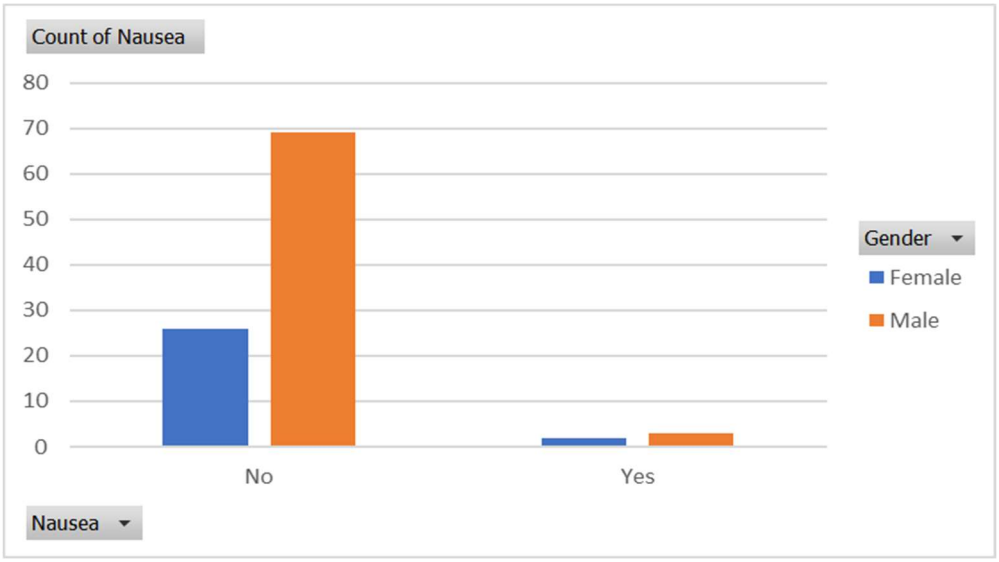
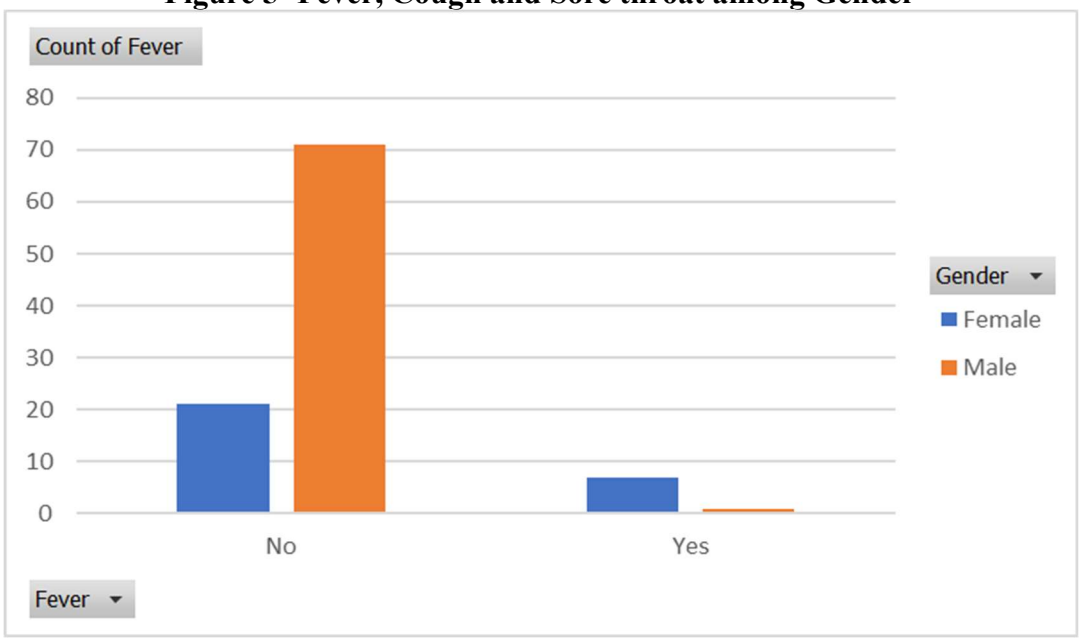


A total no. of 100 subjects completed study. Out of which, 5% subject having Nausea in 2% are female &3% are male and 95% not having Nausea in26 % are female & 69% are male subject.

Data Analysis for 2nd Dose of Covaxin Trial

A total no. of 100 Subjects completed Study. Out of which, the 28 were female and 72 were male, all (100) Subjects are vaccinated for 1st dose & no one is (0%) there who has not been vaccinated for 2nd dose.

Figure 5- Fever, Cough and Sore throat among Gender



A total no. of 100 subjects completed study. Out of which, 8% subject having Fever in 7% are female and 1% are male and 92% not having Fever in 21% are female & 71% are male. 3% subject having

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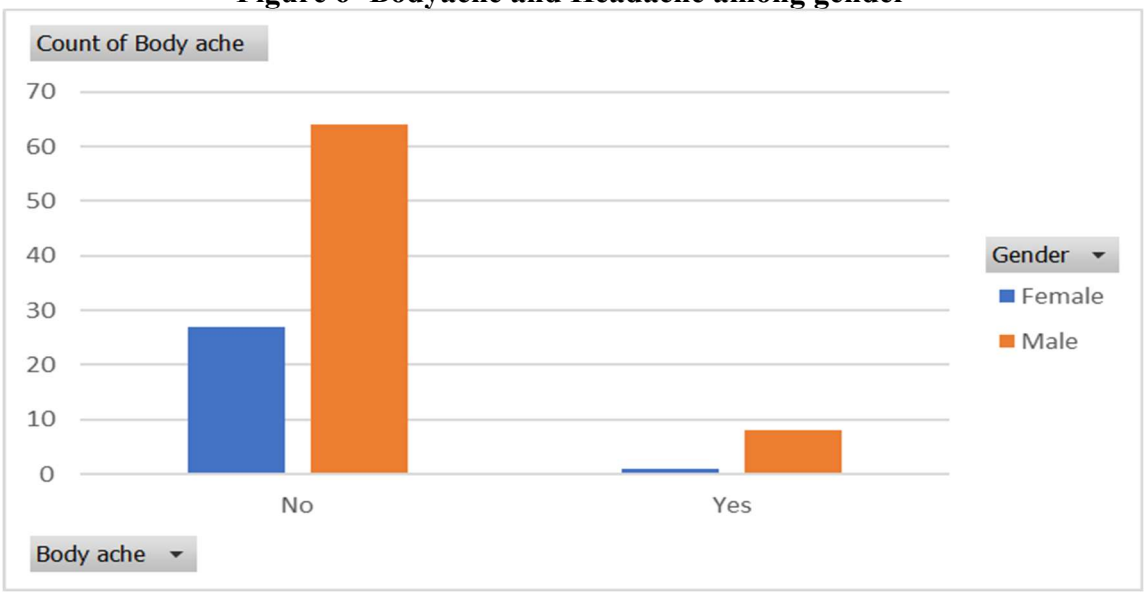
Cough in 2% female & 1% are male and 97% not having Cough in 26% female % & 71% is Male subject. 2% subject having sore throat in 2% are female only and 98% not having sore throat in 26 % female & 72% are male.A total no. of 100 subjects completed study. Out of which, 2% subject having Breathlessness in 2% is only male and 98% not having Breathlessness in 28% female &70% are male subject. 1% subject having Loss of smell in 1% only is male and 99% not having loss of smell in 28% female &71% are male subject.

Figure 6- Bodyache and Headache among gender



Bodyache in 1% female & 8% are male and 91% not having Body ache in 27% female & 64% are male subject. 3% subject having Headache in 1% female &2% are male.92% not having Headache in 27% female & 70% are male subject.

The World Health Organization of Life (WHOQOL)- BREF

Figure -748% suggest good quality of life post vaccination.

ISSN:1624-1940
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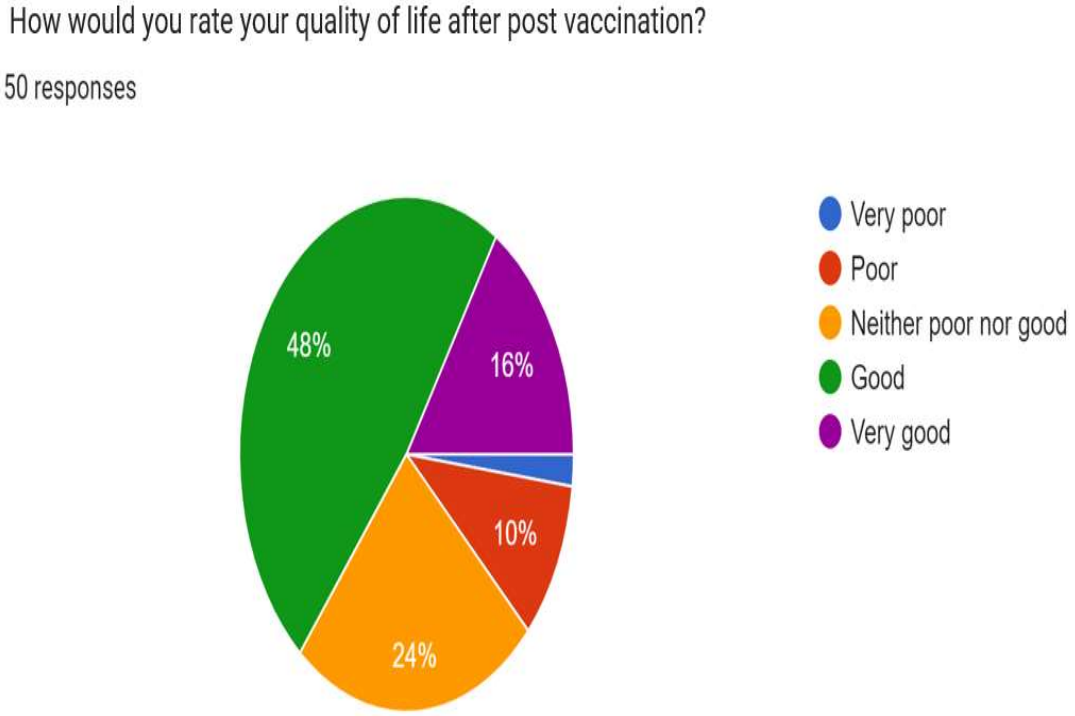

Figure 8-54% were satisfied with their health post vaccination

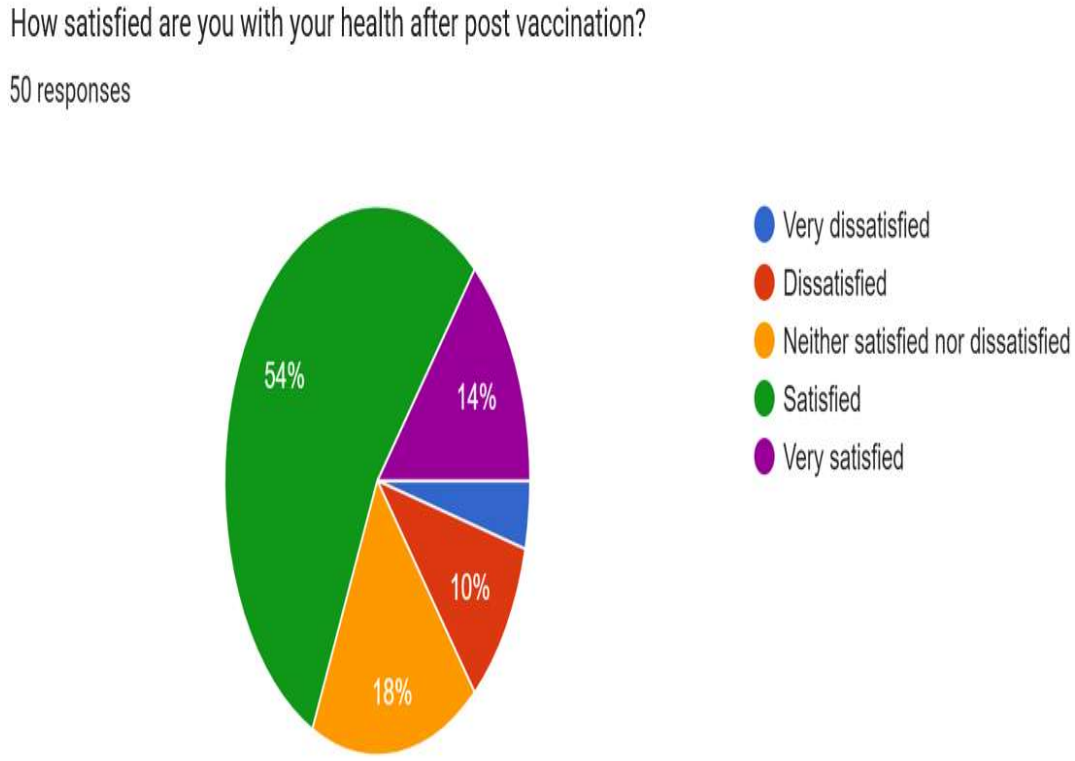

Figure 9-56% enjoy life after post vaccination

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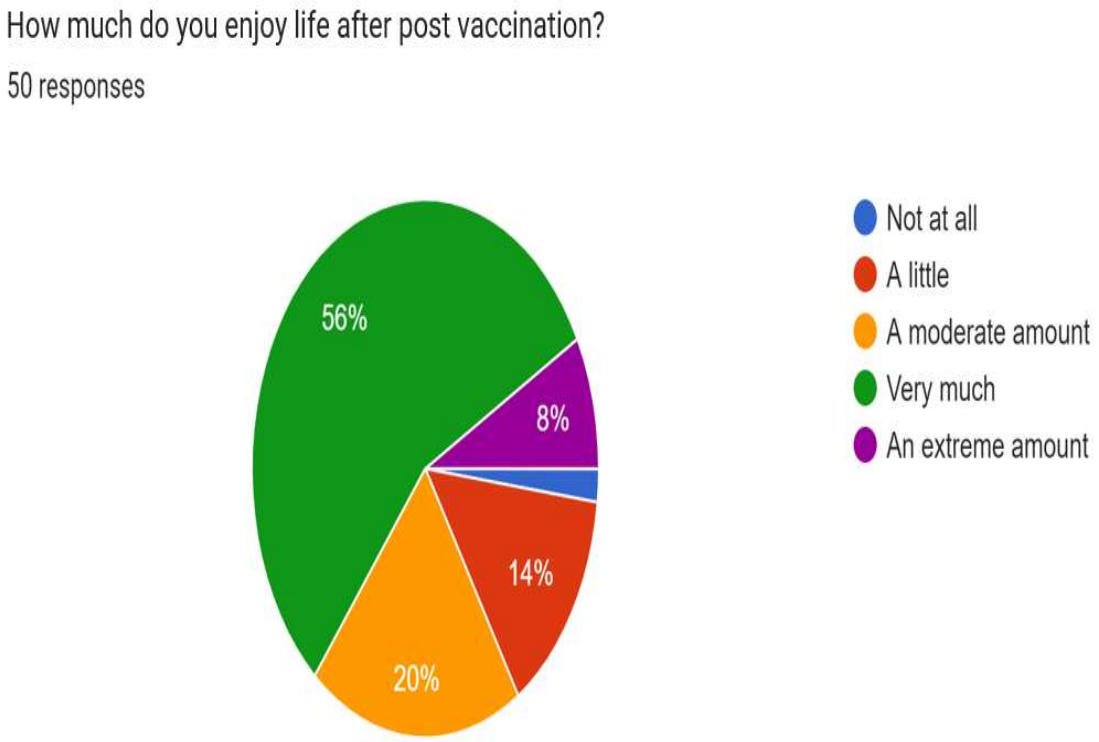

Figure 10-36% had moderately met their needs after post vaccination.75% has satisfied sleep post vaccination.

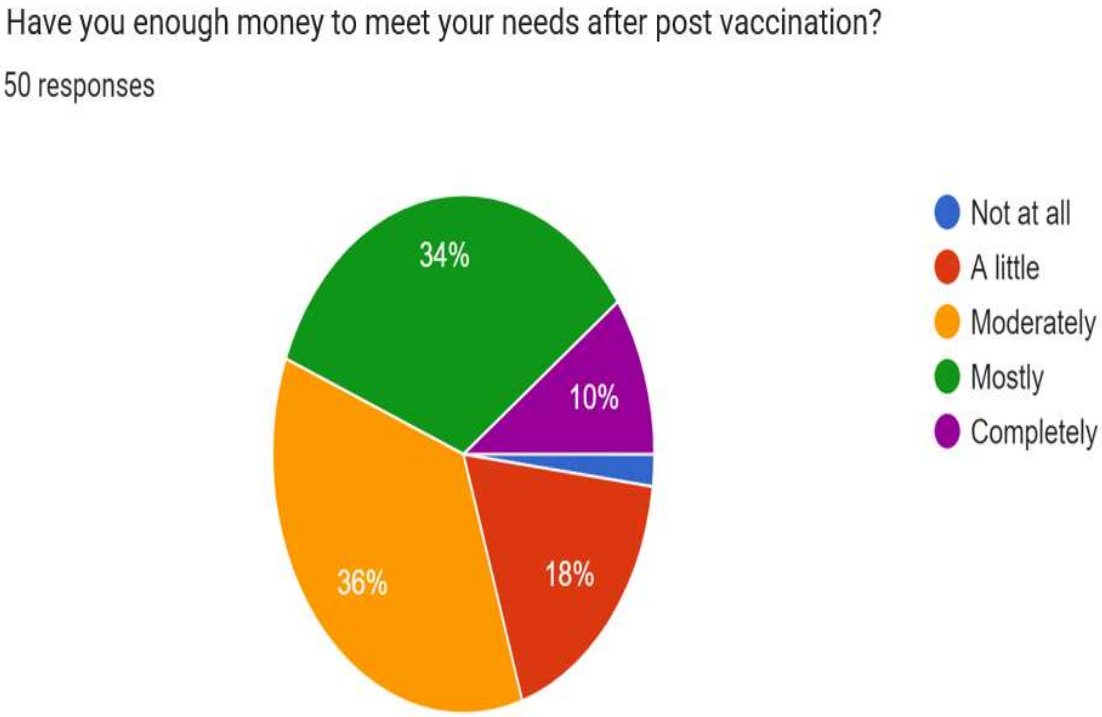

Figure 11-38% had negative feelings very often like depression, anxiety post vaccination

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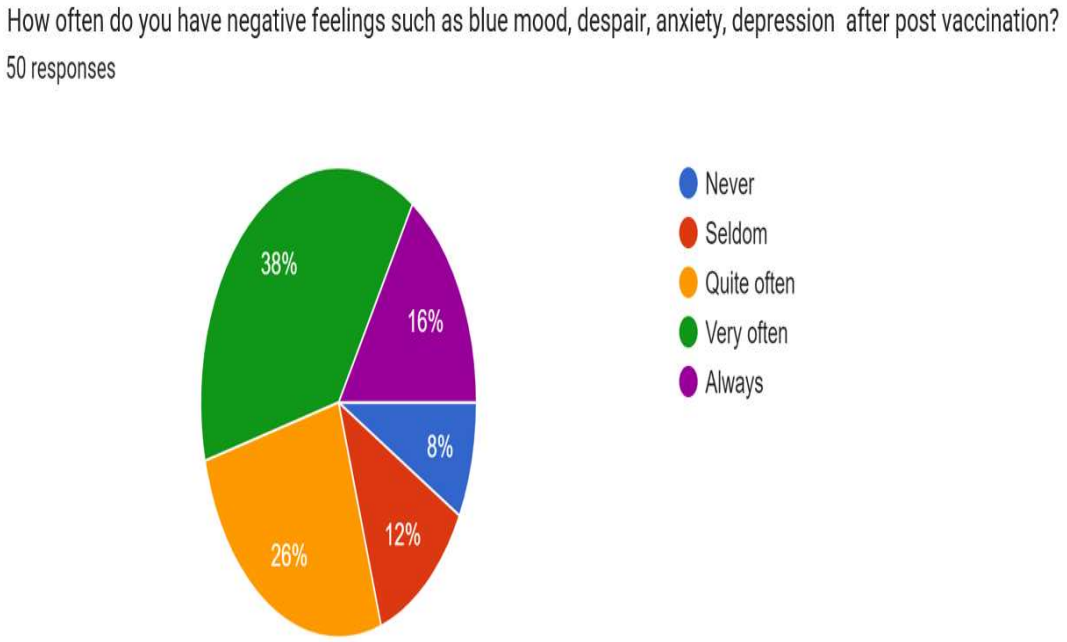

DISCUSSION

Most countries have taken precautionary measures to restrict SARS-CoV-2 transmission from the start of the COVID-19 pandemic in January 2020, in the hopes of speedy creation of safe and effective vaccines. In response, different vaccine candidates have been simultaneously developed and only a few of them were authorized.[4] India is one of the countries that have started an early vaccination campaign as a continuum for its early unprecedented efforts and actions to combat SARS-CoV-2 spread. Despite the availability of the vaccine for the population in India, Another reason for this variation could be related to the usage of a newly emerging technique for some of the COVID-19 vaccines. Thus, in this study, we aimed to evaluate the short-term side effects associated with the COVID-19 vaccines which are currently used in India.[5] In our study, 75% of the participants reported some side effects. The most common side effects were fatigue (60%), pain at the site of injections (55%), followed by fever (15%), and headache (8%). Most of the participants reported having side effects on the first day upon receiving the vaccines (95%) with a one-day duration of the side effects (65%). These findings are very compatible with phase III clinical trial data and vaccine fact sheets, and they are generally reported for those who received the second dosage. In study local pain around the injection site are the most commonly reported side effects, and it occurred on the same day after the injection and lasted for about one day. In a study conducted on participants receiving COVAXIN in India, it was found that 18% of the study participants have reported Body ache.[6] Age of the participants, age nor gender was significantly associated with side effects.[7] In our study, we found that the participants who received the Covaxin reported a significantly higher frequency of fatigue and headache than those who received the Covaxin. Our study has many limitations. The data collected by a self-administered making online questionnaire and this could result in a reporting bias. Because COVID-19 pandemic and the recommendation to continue the social distancing and the preventive measures in India, we preferred to conduct this study as a web-based study to ensure the safety of all study participants. data collection was online as a self-recorded survey, and the distribution of this survey depending on networks. As such, most of the participants were young. It would be insightful if we included more participants who benefited from the Covaxin, but the distribution process at the time of the study for the Covaxin was

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DOI 10.6084/m9.figshare.261151
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limited. Assess the long-term side effects of the corona vaccine due to the inaccessibility of the online questionnaire to the participants.[8,9]

CONCLUSION

The short-term negative effects of COVID-19 vaccines licenced for use in COVAXIN vaccination were investigated in this study. We found that most of the participants reported fever, pain at the site of the injection, body ache, and headache, and they are more common in those after the second dose of the vaccines. A follow-up study on population is warranted to evaluate the safety of the vaccine on the control and prevention of SARS-CoV-2 infection as well as the long-term side effects. There were no SAE that required hospitalization, or a trip to the emergency room.

The World Health Organization of Life (WHOQOL)- BREF Without a doubt, Covaxin vaccines are one of the most life-saving public. According to WHOQOL, satisfied are the capacity for work after vaccination and satisfied are the health-care services after vaccination. A total no. of 100 subjects completed study. Out of which 66% had reported at least one symptom after vaccination. The most prevalent were fiver (20%), Cough (5%), Sore throat (3%), Breathlessness (3%), Loss of smell (2%), Body ache (27%), Headache (11%), Nausea (5%).Covaxin CoV-19 has an acceptable safety profile and has been found to be efficacious against symptomatic COVID-19 in this interim analysis of ongoing clinical trials.

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