International Journal of Clinical Chemistry and Laboratory Medicine (IJCCLM)
Volume 9, Issue 1, 2024, PP 23-31
ISSN No. (Online) 2455-7153
DOI: https://doi.org/10.20431/2455-7153.0901005
www.arcjournals.org

The Immunological Response and Biochemical changes of Covid-19 Vaccine among People Seeking Vaccination at Thika Level 5 Hospital, Kiambu County, Kenya

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Abstract

Coronavirus disease 2019 (COVID-19) is a communicable respiratory disease caused by a new strain of coronavirus that causes illness in humans. The disease spreads from person to person through infected air droplets that are projected through sneezing or coughing. It can also be transmitted when humans have contact with hands or surfaces that have that contain the virus and touch their eyes, nose or mouth with the contaminated hands. COVID-19 was first reported in China, but it has now spread throughout the world. The novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has caused more that 1 million deaths in the first six months of the pandemic and huge economic and social upheaval internationally. An efficacious vaccine is essential to prevent further morbidity and mortality. The goal of vaccine development is to gain direct evidence of vaccine efficacy in protecting humans against SARS-CoV- 2 infection and COVID-19. Most COVID-19 vaccines use messenger RNA (mRNA) based on the principle that coronaviruses have a spike-like structure on their surface called an S protein. COVID-19 Messenger RNA vaccines give cell instructions on how to make a harmless piece of an S protein. After vaccination, cells begin making the protein pieces and displaying them on cell surfaces. The immune system will recognize that the protein is foreign and begins building an immune response which involves production of antibodies.

Data has shown that the vaccine starts working soon after the first dose and has an efficacy rate of 95% seven days after the second dose. This means that about 95% of people who get the vaccine are protected from becoming seriously ill with the virus.

The objective of this study was to determine the level of protection from the COVID-19 vaccine by quantifying the level of immune antibodies and also analysing the biochemical changes associated with the vaccine among the general population. Blood specimen were drawn from the subjects before vaccination (day zero) and analysed for the levels of antobodies quantity test and biochemical changes. The same analysis was done just before the administration of the second dose and six months after the second dose. Using Abbott's Architect i1000 Immunoassy analyser, the SARS-COV-2 IgG antibody levels were determined by establishing the concentration of the antibodies in Arbitrary Units per milliliter (AU/mL), which was eventually extrapolated into antibody titers.Bochemical changes were analysed using a BS-240 Fully automated Clinical Chemistry Analyzer and an electrolyte analyser machines.

The data collected was entered in excel sheets cleaned and then exported to SPSS vversion 29 of 2023 analysis software program for statistical analysis. The study subjects composed of 100 samples where 56 (56%) were male and 44 (44%) female. The subjects sampled were between the age of 20-75years of age, with a mean age group of 25-35 years. Out of these only 2 (2%) had a confirmed covid test previously with the rest 98 (98%) having had not been tested for covid-19. Of the total subjects 10 (10%) had blood pressure, 6(6%) had diabetes and the rest 84 (84%) had no underlying conditions.. There was a statistically significant difference between the change in the levels of antibodies, sodium, potassium, urea, ALT, AST, gamma GT, albumin, direct and indirect bilirubin levels with all having a p-value <0.05. From the study we conclude that the covid-19 vaccine had an immune response due to the increase of IgG antibodies over time, though some increment could have been due to exposer of the virus and not the vaccine directly. The vaccine is safe for administration since the physiological activity on the liver, and kidney were not affected

Keywords: *SARS CoV2-19, Vaccine, Immunity*

1. INTRODUCTION

The FDA has given emergency use authorization to the Pfizer/BioNTech COVID 19 vaccine. (FDA, 2021). Data has shown that the vaccine starts working soon after the first dose and has an efficacy rate of 95% seven days after the second dose. This means that about 95% of people who get the vaccine are protected from becoming seriously ill with the virus. This vaccine is being given to people from the age of 16 years and above and requires two injections given 21 days apart (David L. Rosen, et.al 2020). The Moderna has applied for FDA emergency use authorization of its COVID-19 vaccine. WHO has also given an interim authorization for the use of the Janssen Ad26.Cov 2 S vaccine against COVID-19. Data available has shown that the Morderna Covid-19 vaccine has a 94.1% efficacy rate while the Janssen Ad26.CoV2.S was found to have an efficacy of 85.4% against severe disease and 93.1 % against hospitalization. When administering the Morderna and Pfizer/BioNTech vaccines they should be given in two injections with a 28 days interval while the Janssen AD26.Cov2.S vaccine is a single dose (WHO, 2021). Pfiz-er/BioNTech and Morderna vaccines use the messenger RNA (mRNA) technology and the Janssen AD26.Cov2.S vaccine uses the viral vector technology. The coronaviruses have a spike-like structure (S protein) on their surface, when someone is injected with the COVID-19 mRNA vaccines, the vaccine give cells instructions on how to make a harmless piece of an S protein. On making the harmless S proteins they are displayed on the surfaces of the cells. Once displayed the immune system recognizes them as not belonging the and in response to this the immune sys-tem will produce antibodies against the vaccine (FDA, 2021).

It is important to monitor the long term benefits of a new vaccine to the local population as well as monitor and be on the lookout for any adverse effects. The possible side effects of a COVID-19 vaccine may include Pain, redness or swelling where the shot was given, fever, fatigue, head-ache, muscle pain, chills and joint pain. During the first few days after vaccination, some reaction may happen and these can last for three to four days. The subjects are advised to seek medical advice if they experience any of these allergic reactions which are deemed as side effects of the vaccine. These allergic reaction may include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness (Polack et al., 2020)

Testing has played a critical role in addressing coronavirus disease 2019 (COVID-19) and in the early months of the Covid-19 pandemic, Abbott launched its first SARS-CoV-2 IgG antibody blood test. This test detects the nucleocapsid protein of the virus and has continued to provide a better understanding of the immune response to the virus and the potential duration of the recovery process on victims infected with the virus. Since then, Abbott has deployed an IgM assay that allows for the identification of recent infection and further evaluation of the disease course. Abbott has now achieved a CE Mark for SARS-CoV-2 IgG II Quant, the third laboratory-based serology blood test for the detection of SARS-CoV-2 antibodies. (Abbott, 2020).

The serological testing is targeting IgG antibodies, including neutralizing antibodies, to the receptor binding domain of the S1 subunit of the spike protein of SARS-CoV-2 in serum and plasma and the assay is linear across the analytical measuring interval of 21.0 to 40 000.0 AU/mL (Abbott, 2020). The Clinical Performance has shown 99.60% negative percent agreement and 99.35% positive percent agreement (PPA) in immune-competent patients 15 days post symptoms onset. The assay has shown no cross-reactivity from individuals with other medical conditions, including Human Coronavirus 229E, HKU1, NL63, or OC43.

The assay has achieved a very high level of qualitative agreement in a cohort of samples tested by a plaque reduction neutralization test (PRNT ID50 > 1:20 being positive) and in one cohort study, the PPA of 86 samples was 100%. In addition, there was a demonstrated quantitative relationship of observed neutralizing antibody titers versus the AU/mL values determined in the Quant assay. In this data set a SARS-CoV-2 IgG concentration of 3950 corresponded to a 95% probability of being at or above the PRNT dilution of 1:250 (representative of high titer in this PRNT method) (Shen, 2020). Antibody tests will be used to determine and monitor the subject's immune response to vaccines and also determine how long a response may last. From the data we shall assess whether the antibody levels are a result of the body's natural response to fighting the virus, versus a vaccine-induced response (Adam, L, et.al, 2020)

METHODOLOGY

This was a randomised control study conducted at Thika Level 5 Hospital which is a county referral hospital located in Kiambu County, Thika West District, Thika Municipality division in Biashara sub-location along the General Kago Road. The study subjects of 110 were adults above 18 years of age seeking vaccination at the facility during the study period.

Sample Collection Algorithm

The specimen required was blood where through venous blood collection technique, 3 different tubes were used to collect blood. In one tube about 3-4ml of blood specimen was collected in heparinised vacutainer tube and another 2ml in a sodium citrate vacutainer tube. The blood samples in heparin tube were spun using a centrifuge, serum collected and analysed for COVID-19 antibodies quantification using Abbott Immunoassay machine (Architect i1000 SR). The serum sample was also used to analyse for liver function tests (Albumin, Total protein, Total bilirubin, Direct bilirubin, alkaline phosphatase (ALP), alanine transaminase (ALT), aspartate aminotransferase (AST) and gamma-glutamyl transferase (GGT) and renal function tests (Blood urea nitrogen, creatinine, sodium, potassium and chloride) using C4000 analyser. The sample collected in heparin tube was also used in immune response analysis before and after vaccination. The same procedure was repeated just before the second dose and 3 months after the second dose vaccination.

Laboratory Data Management and Statistical Analysis

The data obtained was entered in an Excel Spreadsheet, cleaned and then exported to SPSS vversion 29 of 2023 analysis software program for statistical analysis. The data was then tested to determine whether it was normally distributed in order to decide the type of statistical analysis to be carried out. Normality or non-normality defined the way the results were to be expressed (mean ± SD or median and range) and the statistics to be used in the data set analysis and comparisons (t test for comparison of means for a pair of data sets, and ANOVA as the cases demanded).

Research Ethics Consideration and Approval

The study Ethical approval was sort from the Jomo Kenyatta University of Agriculture and Technology Ethics and Research Committee (JKUAT-ERC) and National Commission for Science Technology and Innovation (NACOSTI). The study consent approvals were sort from Thika level 5 training department and the Kiambu County directorate of clinical services department.

2. RESULTS

Table 1. *Summary of the means of different parameters at different times.*

	Mean 0	Mean 1	Mean 2
Antibody level	9326.418	14221.017	12991.932
Sodium	144.136	147.581	147.542
Potassium	4.4369	3.8462	3.9236
Chloride	104.043	107.123	106.891
Urea	5.457	7.572	7.430
Creatinine	84.82	87.42	87.03
ALT	24.0325	40.852	37.561
AST	30.11	33.71	33.19
ALP	122.789	113.04	111.59
Gamma GT	37.13	31.99	33.30
Albumin	38.318	42.12	41.62
Total Bil.	19.4420	6.8718	7.9299
Direct Bil.	6.7194	2.0075	2.4055
Total Protein	64.90	64.01	64.06
Valid N (listwise)	100		

The table above shows a summary of the means of different parameters before vaccination (Mean 0), one month after vaccination (Mean 1) and six months after vaccination (Mean 2). From these values, it can be seen that the trend of the parameters over time. Some parameters increased after the first month of vaccination and then their levels started dropping thereafter, resulting to a lower level after six

months. The parameters that had an increase are antibody levels, sodium, chloride, urea, creatine, ALT, AST and albumin. Other parameters decreased upon vaccination and then started rising towards the end of 6 months. These include: Potassium, Gamma GT, total bilirubin, direct bilirubin, and total protein. ALP levels declined then declined even further after 6 months of vaccination. This is in agreement with a study (Elderdery et al., 2022) where he concluded that vaccination affect the immune system and this alters the blood count and other parameters in the body. The study also points out that the vaccine had significant manifestation on the hemopoietic system and thus the abnormalities in the hematological parameters

Determination COVID-19 antibody titters, liver function and kidney function tests among the study subjects at day zero

Table 2. *Results for Day zero before vaccination*

Descriptive Statistics					
	N	Average	Mean	Std. Deviation	Variance
IgG Antibody level(AU/ml)	100	40000.0	9326.418	13237.5978	175233994.997
Sodium (mmol/l)	100	27.6	144.136	6.4543	41.657
Potassium (mmol/l)	100	2.70	4.4369	.65982	.435
Chloride (mmol/l)	100	56.8	104.043	6.5918	43.452
UREA(mmo/l)	100	10.1	5.457	1.8260	3.334
CREATININE(umol/l)	100	101	84.82	19.317	373.159
ALT(U/L)	100	44.40	24.0325	12.49750	156.187
AST(U/L)	100	43	30.11	8.319	69.210
ALP(U/L)	100	189.0	122.789	29.1384	849.046
GAMMA GT(U/L)	100	127	37.13	21.649	468.700
ALBUMIN(g/l)	100	25.0	38.318	5.0831	25.838
TOTAL BIL.(umol/l)	100	97.56	19.4420	15.84065	250.926
DIRECT BIL(umol/l)	100	66.40	6.7194	9.00321	81.058
Total Protein(g/l)	100	48	64.90	10.429	108.758
Valid N (listwise)	100				

Determination of COVID-19 antibody titters, liver function and kidney function tests among the study subjects just before the second dose vaccination

Table 3. *Results for analysis just before second dose vaccination*

Descriptive Statistics					
	N	Average	Mean	Std. Deviation	Variance
Antibody level	100	39979.5	14221.017	14083.8811	198355706.819
Sodium	100	28.4	147.581	7.2101	51.986
Potassium	100	2.30	3.8462	.47372	.224
Chloride	100	117.0	107.123	17.8809	319.725
Urea	100	7.0	7.572	1.6241	2.638
Creatine	100	72	87.42	14.553	211.781
ALT	100	191.6	40.852	46.2178	2136.081
AST	100	27	33.71	7.576	57.400
ALP	100	175	113.04	41.500	1722.281
Gamma GT	100	41	31.99	10.540	111.101
Albumin	100	25	42.12	5.405	29.218
Total Bil.	100	40.20	6.8718	8.51485	72.503
Direct Bil.	100	5.74	2.0075	1.31798	1.737
Tottal Protein	100	61	64.01	11.366	129.182
Valid N (listwise)	100				

Determination COVID-19 antibody titters, liver function, kidney function tests among the study subjects 3 months post second dose vaccination

Table 4. *Results for analysis 3months after the second dose vaccination*

Descriptive Statistics					
	N	Average	Mean	Std. Deviation	Variance
Antibody level	100	36757.9	12991.932	11208.1131	125621800.028

Sodium	100	29.3	147.542	6.9125	47.782
Potassium	100	2.30	3.9236	.53089	.282
Chloride	100	134.8	106.891	18.0943	327.404
Urea	100	8.9	7.430	1.6433	2.701
Creatine	100	86	87.03	15.874	251.989
ALT	100	191.6	37.561	43.0190	1850.634
AST	100	28	33.19	7.553	57.044
ALP	100	175	111.59	40.819	1666.184
Gamma GT	100	86	33.30	13.094	171.465
Albumin	100	25	41.62	5.482	30.056
Total Bil.	100	44.93	7.9299	9.82872	96.604
Direct Bil.	100	13.74	2.4055	2.32602	5.410
Tottal Protein	100	61	64.06	11.280	127.229
Valid N (listwise)	100				

Pairwise comparison of the COVID-19 antibodies and Biochemical changes at day zero, just before the second dose and 3 months after the second dose vaccination.

Pairwise Comparison

The study also aimed at comparing the antibody levels, chemistry parameters in pairwise method. This was aimed at determining if there was any significance in the changes of these parameters in relation to vaccination and over time period.

Table 5. *Pairwise comparisons for Antibody level*

Pairwise Comparisons						
Measure: Antibody_Level						
(I) time	(J) time	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
1	2	-4894.599*	1620.703	.010	-8841.560	-947.638
	3	-3665.514	1557.447	.062	-7458.426	127.398
2	1	4894.599*	1620.703	.010	947.638	8841.560
	3	1229.085	615.016	.145	-268.688	2726.858
3	1	3665.514	1557.447	.062	-127.398	7458.426
	2	-1229.085	615.016	.145	-2726.858	268.688
Based on estimated marginal means						
*. The mean difference is significant at the .05 level.						
b. Adjustment for multiple comparisons: Bonferroni.						

From the table, it can be seen that the mean differences between time 1 and time 2, time 1 and time 3 and time 2 and time 3. The mean differences between time 1 and time 2 (before vaccination and one month after vaccination) were found to be significant (mean = -4894.599, p-value = 0.01<0.05). this suggests that there was a significant change in antibody levels after vaccination. However, between time 1 and time 3 (six months after vaccination), there seems to be no significant change in antibody level (mean difference = -3665.514, p-value = 0.062>0.05). However, this appears to be more significant compared to the mean differences between time 2 and time 3 (between one and six months after vaccination) (mean difference = 1229.085, p-value = 0.145>0.05). This decrease in antibody level was not statistically significant at a 5% level of significance (95% confidence interval).

Table 6. *Pairwise Comparisons for Chemistry Measures*

Variable	Time	Mean Differences	P-value	Significance
Sodium	1-2	-3.445	0.001	Significant
	1-3	-3.406	0.001	Significant
	2-3	0.039	1.00	Not significant
Potassium	1-2	0.591	0.000	Significant
	1-3	0.513	0.000	Significant
	2-3	-0.077	0.142	Not significant
Chloride	1-2	-3.080	0.289	Not significant
	1-3	-2.848	0.403	Not significant

	2-3	0.232	1.00	Not significant
Urea	1-2	-2.115	0.000	Significant
	1-3	-1.973	0.000	Significant
	2-3	0.142	0.543	Not significant
Creatinine	1-2	-2.6	0.803	Not significant
	1-3	-2.21	1.00	Not significant
	2-3	0.39	1.00	Not significant
SGPT	1-2	-16.82	0.002	Significant
	1-3	-13.529	0.01	Significant
	2-3	3.291	0.401	Not significant
SGOT	1-2	-3.6	0.004	Significant
	1-3	-3.08	0.019	Significant
	2-3	0.52	0.893	Not significant
ALP	1-2	9.749	0.201	Not significant
	1-3	11.199	0.095	Not significant
	2-3	1.45	1.00	Not significant
Gamma GT	1-2	5.14	0.98	Not significant
	1-3	3.83	0.44	Not significant
	2-3	-1.31	0.475	Not significant
Albumin	1-2	-3.802	0.00	Significant
	1-3	-3.302	0.00	Significant
	2-3	0.5	0.36	Not significant
Total bilirubin	1-2	12.57	0.00	Significant
	1-3	11.512	0.00	Significant
	2-3	-1.058	0.531	Not significant
Direct Bilirubin	1-2	4.712	0.00	Significant
	1-3	4.314	0.00	Significant
	2-3	-0.398	0.197	Not significant
Total protein	1-2	0.89	1.00	Not significant
	1-3	0.84	1.00	Not significant
	2-3	-0.05	1.00	Not significant

The table above shows the pairwise comparisons of the mean differences for sodium levels between time 1 and time 2, time 1 and time 3 and time 2 and time 3. The mean differences between time 1 and time 2 were found to be significant (mean =-3.445, p-value = 0.001 < 0.05). This suggests that there was a significant change in sodium levels after vaccination. The same was true between time 1 and time 3 (mean difference = -3.406, p-value = 0.001 < 0.05), but the results were not significant between time 2 and time 3 (mean difference =0.039, p-value = 1.0 > 0.05) at a 5% level of significance. This suggests a significant change in sodium levels between times 1 and 2 and 1 and 3, but not between 2 and 3.

The mean differences between time 1 and time 2 were found to be significant (mean = 0.591, p-value = 0.000<0.05). This suggests that there was a significant change in potassium levels after vaccination. The same was true between time 1 and time 3 (mean difference = 0.513, p-value = 0.000<0.05), but the results were not significant between time 2 and time 3 (mean difference = -0.077, p-value = 0.142>0.05) at 5% level of significance. This suggests a significant change in potassium levels between times 1 and 2 and 1 and 3, but not between 2 and 3.

On the mean differences of chloride levels between time 1 and time 2, time 1 and time 3 and time 2 and time 3. None of the mean differences between the given times were found to be significant. The mean differences between time 1 and time 2 (mean differences =-3.08, p-value = 0.289>0.05) and between time 1 and time 3 (mean difference = -2.848, p-value = 0.403>0.05) while between time 2 and time 3 (mean difference =0.232, p-value = 1.0>0.05). The increase in chloride levels between time 1 and time 2 and the slight decrease between time 2 and time 3 were not statistically significant at 5% level of significance.

Similarly, on the pairwise comparisons of the mean differences for urea levels between time 1 and time 2, time 1 and time 3 and time 2 and time 3. The mean differences between time 1 and time 2 were found to be significant (mean = -2.115, p-value = 0.000<0.05). This suggests that there was a significant increase in urea levels after vaccination. The same was true between time 1 and time 3 (mean difference

= -1.973, p-value = 0.000<0.05), but the results were not significant between time 2 and time 3 (mean difference = 0.142, p-value = 0.543>0.05) at 5% level of significance. This suggests a significant change in urea levels between times 1 and 2 and 1 and 3, but not between 2 and 3.

Again on the mean differences in Creatinine levels between time 1 and time 2, time 1 and time 3 and time 2 and time 3. None of the mean differences between the given times were found to be significant. The mean differences between time 1 and time 2 (mean differences =-2.6, p-value = 0.803>0.05) and between time 1 and time 3 (mean difference = -2.21, p-value = 1.0>0.05) while between time 2 and time 3 (mean difference =0.39, p-value = 1.0>0.05). The increase in creatinine levels between time 1 and time 2 and the slight decrease between time 2 and time 3 were not statistically significant at a 5% level of significance.

The table also shows a pairwise comparisons of the mean differences for SGPT levels between time 1 and time 2, time 1 and time 3 and time 2 and time 3. The mean differences between time 1 and time 2 were found to be significant (mean = -16.82, p-value = 0.02<0.05). This suggests that there was a significant increase in SGPT levels after vaccination. The same was true between time 1 and time 3 (mean difference = -13.529, p-value = 0.01<0.05), but the results were not significant between time 2 and time 3 (mean difference = 3.291, p-value = 0.401>0.05) at 5% level of significance. This suggests a significant change in SGPT levels between times 1 and 2 and times 1 and 3, but not between times 2 and 3.

On the pairwise comparisons of the mean differences for SGOT levels between time 1 and time 2, time 1 and time 3 and time 2 and time 3. The mean differences between time 1 and time 2 were found to be significant (mean = -3.6, p-value = 0.004<0.05). This suggests that there was a significant increase in SGOT levels after vaccination. The same was true between time 1 and time 3 (mean difference = -3.08, p-value = 0.019<0.05), but the results were not significant between time 2 and time 3 (mean difference = 0.52, p-value = 0.893>0.05) at 5% level of significance. This suggests a significant change in SGOT levels between times 1 and 2 and 1 and 3, but not between 2 and 3.

The table also shows the mean differences of ALP levels between time 1 and time 2, time 1 and time 3 and time 2 and time 3. None of the mean differences between the given times were found to be significant. The mean differences between time 1 and time 2 (mean differences =9.749, p-value = 0.201>0.05) and between time 1 and time 3 (mean difference = 11.199, p-value = 0.095>0.05) while between time 2 and time 3 (mean difference =1.45, p-value = 1.0>0.05). The increase in ALP levels between time 1 and time 2 and the slight decrease between time 2 and time 3 were not statistically significant at 5% level of significance.

Again on the mean differences of Gamma GT levels between time 1 and time 2, time 1 and time 3 and time 2 and time 3. None of the mean differences between the given times were found to be significant. The mean differences between time 1 and time 2 (mean differences = 5.14, p-value = 0.0.98>0.05) and between time 1 and time 3 (mean difference = 3.83, p-value = 0.44>0.05) while between time 2 and time 3 (mean difference = -1.31, p-value = 0.475>0.05). The decrease in Gamma GT levels between time 1 and time 2 and the slight increase between time 2 and time 3 were not statistically significant at a 5% level of significance.

Table also shows the pairwise comparisons of the mean differences for albumin levels between time 1 and time 2, time 1 and time 3 and time 2 and time 3. The mean differences between time 1 and time 2 were found to be significant (mean = -3.802, p-value = 0.000<0.05). This suggests that there was a significant increase in albumin levels after vaccination. The same was true between time 1 and time 3 (mean difference = -3.302, p-value = 0.000<0.05), but the results were not significant between time 2 and time 3 (mean difference = 0.5, p-value = 0.36>0.05) at 5% level of significance. This suggests a significant change in AST levels between times 1 and 2 and 1 and 3, but not between 2 and 3.

The pairwise comparisons of the mean differences for total bilirubin levels between time 1 and time 2, time 1 and time 3 and time 2 and time 3 was also demonstrated. The mean differences between time 1 and time 2 were found to be significant (mean =12.57, p-value = 0.000<0.05). This suggests that there was a significant increase in total bilirubin levels after vaccination. The same was true between time 1 and time 3 (mean difference = 11.512, p-value = 0.000<0.05), but the results were not significant between time 2 and time 3 (mean difference = -1.058, p-value = 0.531>0.05) at 5% level of significance.

This suggests a significant change in total bilirubin levels between times 1 and 2 and 1 and 3, but not between 2 and 3.

Table also shows the pairwise comparisons of the mean differences for total bilirubin levels between time 1 and time 2, time 1 and time 3 and time 2 and time 3. The mean differences between time 1 and time 2 were found to be significant (mean = 4.712, p-value = 0.000<0.05). This suggests that there was a significant increase in direct bilirubin levels after vaccination. The same was true between time 1 and time 3 (mean difference = 4.314, p-value = 0.000<0.05), but the results were not significant between time 2 and time 3 (mean difference = -0.398, p-value = 0.197 >0.05) at 5% level of significance. This suggests a significant change in direct bilirubin levels between times 1 and 2 and 1 and 3, but not between 2 and 3

None of the mean differences between the given times were found to be significant. The mean differences between time 1 and time 2 (mean differences = 0.89, p-value = 1.0 >0.05) and between time 1 and time 3 (mean difference = 0.84, p-value = 1.0>0.05) while between time 2 and time 3 (mean difference = 0.5, p-value = 1.0>0.05). The decrease in protein levels between time 1 and time 2 and the slight increase between time 2 and time 3 were not statistically significant at 5% level of significance.

3. Discussion

The current study was able to make use of whole blood, plasma and serum as the specimens of choice since these are the type of specimens used for analysis of antibodies, D-dimer, liver function, renal function and full blood cell count in a routine clinical laboratory. The anticipation of the study was to reveal whether there is an immune response demonstrated by the rise of the IgG antibodies and also whether there was any physiological effect of in the liver and kidney and/or any hematological changes upon vaccination. For the objectives to be achieved the subjects needed to be tested before and after vaccination and then a follow-up to ascertain if the changes were attributed to the vaccination.

On analyzing the immunogenicity of the subjects and the neutralizing antibodies estimated. From the study we found that before the initiation of the vaccine more than 3/4 of the subjects had elevated levels of IgG Covid-19 antibodies this being an indication of previous exposure to the virus. Although the Immunogenicity data showed the vaccines elicited immune responses on three doses, the immune response could not only be associated with the vaccination only since the titter of the study subjects was elevated before vaccination was initiated. Therefore, we reject the null hypothesis with a static of -2.9875807072245384 and a p-value of 0.0035452306854575314. This therefore shows that there is need for vaccine booster after every 6 months to ensure continual protection against the virus. This could be associated with the mutation associated with virus. This agrees with a study done on vaccination immunogenicity and booster vaccination.

The liver and renal function tests were also carried out to assess the physiological effect of the vaccine. From our study we found that there was a significant change in potassium, sodium, BUN, ALT, AST, Albumin and bilirubin levels. This agrees with other studies done on safety of the covid-19 vaccines (Frenck et al., 2021) which concluded that there were biochemical changes associated with vaccination though the severity of these reactions was moderate.

4. Conclusion and Recommendation

From the current study findings it is very clear that the immune response was due to the vaccination given to the subjects and this correlates with another study done by (Keshavarz et al., 2022) that depicted that there is humoral immune response elicited following vaccination. The study also correlates to another study (Zhang et al., 2021) that the level of antibodies alone cannot be used as key indicator of successful Covid-19 vaccine rather as a recallable specific immune response to SARS-CoV 2, thus a continuous monitoring is necessary. This will ensure that the vaccinated individuals are given a booster of the vaccine after 6 months as the antibody titers decrease over time from the results in this study.

In summary there was a sustainable immune response triggered by administration of the vaccine and this is in support of emergency of approval use of the vaccines. The results correlates with a study (Uysal et al., 2022) that concluded that antibodies that increased due to vaccination or Covid-19 infections, remained in circulations for a certain period of time. From our study the increase in antibodies after the second dose was not statistically significant and this is in agreement with previous

studies (Uysal et al., 2022) that concluded that there was a decrease in antibody titers post vaccination. The physiological effect was well tolerated and induced humoral responses against SARS-CoV-2, which supported the approval for use of the vaccine.

In conclusion the current study recommends administration of booster shots after every 6months to ensure that the level of IgG antibodies titer is kept at a level that would offer immunity.

We recommend further studies on the T-lymphocyte and B-lymphocyte response on the administration of the vaccine. We also recommend bi annual monitoring of the vaccinated individuals to amonitor the IgG titters and also to monitor biochemical changes that may arise after vaccination or booster vaccination.

REFERENCES

[1] Elderdery, A. Y., Elkhalifa, A. M. E., Alsrhani, A., Zawbaee, K. I., Alsurayea, S. M., Escandarani, F. K., Alhamidi, A. H., Idris, H. M. E., Abbas, A. M., Shalabi, M. G., & Mills, J. (2022). Complete Blood Count Alterations of COVID-19 Patients in Riyadh, Kingdom of Saudi Arabia. *Journal of Nanomaterials*, *2022*. https://doi.org/10.1155/2022/6529641

[2] FDA. (2021). FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine. *FDA News Release*, *December*. https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine

[3] Frenck, R. W., Klein, N. P., Kitchin, N., Gurtman, A., Absalon, J., Lockhart, S., Perez, J. L., Walter, E. B., Senders, S., Bailey, R., Swanson, K. A., Ma, H., Xu, X., Koury, K., Kalina, W. V., Cooper, D., Jennings, T., Brandon, D. M., Thomas, S. J., … Gruber, W. C. (2021). Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents. *New England Journal of Medicine*, *385*(3), 239–250. https://doi.org/10.1056/nejmoa2107456

[4] Heinz, F. X., & Stiasny, K. (2021). Distinguishing features of current COVID-19 vaccines: knowns and unknowns of antigen presentation and modes of action. *Npj Vaccines*, *6*(1). https://doi.org/10.1038/s41541-021-00369-6

[5] Keshavarz, B., Richards, N. E., Workman, L. J., Patel, J., Muehling, L. M., Canderan, G., Murphy, D. D., Brovero, S. G., Ailsworth, S. M., Eschenbacher, W. H., McGowan, E. C., Mann, B. J., Nelson, M. R., Kadl, A., Woodfolk, J. A., Platts-Mills, T. A. E., & Wilson, J. M. (2022). Trajectory of IgG to SARS-CoV-2 After Vaccination With BNT162b2 or mRNA-1273 in an Employee Cohort and Comparison With Natural Infection. *Frontiers in Immunology*, *13*(March), 1–9. https://doi.org/10.3389/fimmu.2022.850987

[6] Polack, F. P., Thomas, S. J., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., Perez, J. L., Pérez Marc, G., Moreira, E. D., Zerbini, C., Bailey, R., Swanson, K. A., Roychoudhury, S., Koury, K., Li, P., Kalina, W. V., Cooper, D., Frenck, R. W., Hammitt, L. L., … Gruber, W. C. (2020). Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *New England Journal of Medicine*, *383*(27), 2603–2615. https://doi.org/10.1056/nejmoa2034577

[7] Uysal, E. B., Gümüş, S., Bektöre, B., Bozkurt, H., & Gözalan, A. (2022). Evaluation of antibody response after COVID-19 vaccination of healthcare workers. *Journal of Medical Virology*, *94*(3), 1060–1066. https://doi.org/10.1002/jmv.27420

[8] Waithaka, S. K., Njagi, E. N. M., Ngeranwa, J. J. N., Mwangi, D. M., Chiuri, B. M., Njagi, L. J., & Gatua, W. K. (2010). Quantitative reference ranges for fasting profiles and oral glucose tolerance test for healthy adults in metropolitan region of Nairobi, Kenya. *International Journal of Health Research*, *3*(1), 13–19.

[9] Zhang, Y., Zeng, G., Pan, H., Li, C., Hu, Y., Chu, K., Han, W., Chen, Z., Tang, R., Yin, W., Chen, X., Hu, Y., Liu, X., Jiang, C., Li, J., Yang, M., Song, Y., Wang, X., Gao, Q., & Zhu, F. (2021). Safety, tolerability, and immunogenicity of an inactivated SARS-CoV-2 vaccine in healthy adults aged 18–59 years: a randomised, double-blind, placebo-controlled, phase 1/2 clinical trial. *The Lancet Infectious Diseases*, *21*(2), 181–192. https://doi.org/10.1016/S1473-3099(20)30843-

Citation: *Joyce Gachoki et al. The Immunological Response and Biochemical changes of Covid-19 Vaccine among People Seeking Vaccination at Thika Level 5 Hospital, Kiambu County, Kenya. International Journal of Clinical Chemistry and Laboratory Medicine (IJCCLM). 2024; 9(1):23-31. DOI: http://dx.doi.org/10.20431/2455-7153.0901005.*