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Investigation of Some Biochemistry Markers in COVID-19 Vaccinated Iraqi Individuals

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Abstract

Background: Serious intense respiratory disorder Covid-19 is a causing respiratory infection known as Corona virus. This novel corona virus transmits from one human to another and has caused significant mortality overall prompting the continuous pandemic. Also, illness seriousness varies extensively from one person to another. **Subjects**: fifty individuals (n = 100) with age ranged (20-65 years) were enrolled in this study. Laboratory parameters were performed of baseline and 14 days after first dose and 14 days after second dose from covid-19 vaccination. **Results**: All people in this study received the Pfizer-BioNTech vaccine and none systematic side effects were observed in vaccinated subjects during the study period. **Conclusions**: From the results of present study, conclusions could be that all parameters are non-significant and without the appearance of abnormal biochemical signs or increase in coagulation or changes in basic body functions following the received the Pfizer vaccine.

Keywords: biochemistry markers, COVID-19 vaccinated, SARS-Cov-2 vaccination, Respiratory distress in covid individuals, Covid mortality and pandemic.

1. Introduction

The corona virus disease 2019 is pandemic "it upsets our ordinary life and had critical ramifications for human health. Preventive public health measures such as mask usage, physical distancing, and enhanced sanitation procedures are necessary to alleviate strain on the health system and reduce community transmission, while advances in therapeutic development have potentially improved clinical outcomes for patients with severe illness". However, "minimizing the risk of resurgence and enabling a safe return to normal life will require a majority of the population to develop immunity against SARS-CoV-2 (severe acute respiratory syndrome corona virus 2, the virus that causes COVID-19)". Acceptably achieving this level of herd immunity quickly will likely require the development of safe and effective vaccines [1].

All things considered, the accentuation on speed has incited public tension with regards to the security and viability of vaccines created on sped up timetables. "Among the concerns is that the regulatory standards for approval will be lowered under political pressure for a vaccine. In a recent poll of 1056 US adults, 31% indicated that they are uncertain about whether they would receive a potential COVID-19 vaccine and 20% indicated they would choose not to take it, with concerns about safety and adverse effects being the primary reason for avoiding vaccination", [2 , 3].

First and foremost, "FDA is committed to ensuring that any vaccine is manufactured in accordance with all of FDA's quality standards and that its safety and effectiveness are verified before being authorized or licensed. To ensure that a widely deployed vaccine is effective, FDA has specifically recommended in its guidance to vaccine developers that the primary efficacy endpoint point estimate for a placebo-controlled efficacy trial should be at least 50%, and the statistical success criterion should be that the lower bound of the appropriately alpha-adjusted confidence interval (CI) around the primary efficacy endpoint point estimate is >30%.5 In other words, the lower limit of a 95% CI would have to be greater than 30%" [4].

Second, "to achieve population-wide immunity, a COVID-19 vaccine would need to be widely deployed. It is therefore critical that the data derived from nonclinical and clinical studies clearly demonstrate that the vaccine is safe and effective for

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widespread use. Also acknowledging the need for broad use, FDA recognizes that the pandemic has sufficient representation of racial and ethnic minorities, older adults, and individuals with medical co-morbidities in the clinical trials". The inclusion "of diverse populations, including older individuals, in trials is necessary for a comprehensive assessment of product safety and effectiveness and to properly inform clinical decision-making [5]. Vaccines are central to present day general health. Evidence "from the 20th century demonstrates how the broad uptake of immunization can eliminate or reduce the risk of infectious disease outbreaks. Smallpox has been eradicated from the globe, and polio has now been eliminated from most countries". "The likelihood of harm from seasonal pathogens such as influenza has also been reduced". Affirming, maintaining, and ensuring "FDA's commitment to rigorous scientific review will enable COVID-19 vaccines to contribute to this important public health legacy"[5]. Vaccine "development and use depend on data-driven assessment of benefits and risks, first by regulatory bodies, and then more subjectively, millions of times over, by individual physicians and patients". Some vaccines "have transformed public health (polio, smallpox, measles), whereas others have failed to work (HIV, malaria) or were later found to have important unexpected adverse effects (rotavirus, the 1976 influenza vaccine)"[6]. "As with drugs, the efficacy and safety of a vaccine are not binary. Each will fall along agradient and be subject to varying definitions over time".In its June 2020 "guidance document, the FDA established its expectation that an approved vaccine would reduce the occurrence or severity of disease in at least 50% of recipients, a standard similar to that for annual influenza vaccines"[7].

2. Materials and Methods

Fifty individuals (n = 100) with age ranged (20-65 years) were enrolled in this study. Laboratory disproportionately affected many populations and strongly recommends that investigators ensure parameters were performed of baseline and 14 days after first dose and 14 days after second dose from covid-19 vaccination, the duration between the first and second doses is 21 days.Ten milliliters of venous blood was drawn, that placed in a plane tube, left for (15 min), the serum that obtained after of venous blood centrifuged and stored at (-20oC) unless used immediately. Whole blood (vacuum tubes containing sodium citrate) was used in determination of d.dimer test. Total Serum Bilirubin (T.S.B), Aspartate Transaminases (AST), Alanine Transaminases (ALT), Alkaline Phosphatase (ALP), Gamma-glutamyltransferase (GGT), Total Protein ,Albumin, LDH enzyme , Urea, creatinine , Uric Acid, Amylase, Lipase, D.Dimer, C-reactive protein and F.B.Swere estimated by using a Kit method (products of Roche Diagnostics, Germany) on automatic Roche CobasC311 analyzer [8].Serum ferritin levels were assayed by immunoassay through the Cobas E411 analyzer (Roche, Germany) [9].The reference ranges for these analytes were obtained from the kit manufacturers. Serum IL-6 levels were measured using ELISA kit (Ray Bio Human IL-6 for in vitro quantitative measurement of human IL6 in serum) [10], according to the manufactures protocol.

Statistically no significant considered when P-values was >0.05 and significant when P-values was <0.005.

3. Results and discussion

All the symptoms manifestations announced by the received the vaccine subjects were headache, joint pain, muscle fatigue or fever during the following days after vaccination. In Tables (1, 2) there are all the parameters. None of the result showed critical significant after vaccination. Exception was for C-receptive protein that showed a slight increment after first dose (Table 2).

Table 1: The Descriptive Parameters

Parameters	Baseline	First dose	Second dose	P-Value
T.S.B (mg/dl)	0.63 ± 0.312	0.72± 0.227	0.66± 0.264	0.30
AST (U/l)	14.88± 9.558	15.66 ± 10.062	15.11 ± 9.867	0.105
ALT (U/l)	14.33± 8.746	15.88± 8.506	14.88± 5.925	0.30
ALP (U/l)	75.77± 28.247	76.88 ± 26.417	74.55 ± 27.735	0.268
GGT (U/l)	18.44 ± 6.784	20.55 ± 6.146	19.55 ± 5.525	0.08
Total Protein(g/dl)	70.80± 5.921	70.70 ± 6.429	71.30± 6.165	0.466
Serum albumin(g/dl)	4.44 ± 0.758	4.53 ± 0.805	4.50 ± 0.618	0.107
Urea (mg/dl)	26.00 ± 11.249	27.41 ± 11.835	27.83 ± 11.093	0.383
Creatinine(mg/dl)	0.81 ± 0.215	0.86± 0.172	0.85 ± 0.170	0.294
Uric acid (mg/dl)	5.04± 1.247	5.18 ± 1.212	5.089± 1.143	0.400
Amylase (U/l)	45.6± 22.187	46.4± 19.681	45.2± 20.617	0.466
Lipase (U/l)	35.7± 17.327	37.1± 17.678	37.5± 16.345	0.430
F.B.G (mg/dl)	93.00 ± 9.018	95.00 ± 8.246	95.10 ± 7.680	0.305

Table 2:The Descriptive Parameters

Parameters	Baseline	First dose	Second dose	P-Value
D.dimer (ng/mL)	191.6 ± 61.085	228.9 ± 76.229	241.5± 73.842	0.121
Ferritin (ng/mL)	96.9± 63.755	112.0 ± 57.813	122.5± 70.171	0.202
IL-6 (Pg/mL)	11.07± 3.787	12.6± 2.458	12.5± 2.273	0.149
C.R.P (mg/dl)	4.96± 2.488	11.1± 5.704	6.5± 2.415	0.004
LDH (U/l)	158.6 ± 19.878	173.9 ± 20.967	171.5 ± 16.433	0.055

The above results did not show relation between vaccination and coagulation. The limits of review: First, while the examined populace was treated with the Pfizer vaccine, most coagulation occasions were accounted for the AstraZeneca but few have been all the more as of late revealed even with the Pfizer vaccine. The other subject, the development after vaccination was generally limited to evaluate the genuine commonness of rare side effects. In any case, it ought to be perceived that the majority of reported events do happen inside the time of 14 days after immunization. It is consequently far-fetched that we missed clinically significant events. Finally, the investigated population was not on anticoagulant treatment and was free from known risk factors of thrombosis; it is therefore unknown whether the similar conclusions apply to subjects with known abnormalities of coagulation or unknown. All in all, the study shows no alterations and not presence of abnormal biochemical markers or increase in coagulation or changes in basic body functions following vaccine receiving. Until new data is accessible the above information supports the assertion “on the safety of vaccination for SARS-Cov-2, recently issued by the International Society on Thrombosis and Haemostasis” [11, 12].

4.Conclusions

Conclusions could be that all measured parameters are non-significant and not presence of abnormal biochemical markers or increase in coagulation or changes in basic body Functions were monitored following the received of the Pfizer vaccine. Exceptions were for C- reactive protein that showed a slight increase after first dose.

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