CLINICAL AND LABORATORY FEATURES OF VACCINATION AGAINST COVID-19 IN PREGNANT WOMEN

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Reactogenicity
Immunogenicity

Abstract

Objective: to evaluate the safety, efficacy, and immunogenicity of COVID-19 vaccination in pregnant women.

Materials and research methods. The study included 120 pregnant women vaccinated with the Gam-Kovid-Vak vaccine against COVID-19. Of these, 60 women were vaccinated in the second trimester of pregnancy (main group I) and 60 in the third trimester of pregnancy (main group II), and the comparison group consisted of 30 pregnant women who refused vaccination.

The study used clinical, immunological, hormonal, ultrasound, Doppler and statistical research methods.

Results and its discussion. Analysis of post-vaccination reactogenicity in women vaccinated against COVID-19 showed the manifestation of very weak local and general reactions, the formation of immunogenicity up to 87%, the analysis of the hormonal status and the fetoplacental system did not reveal pronounced pathological abnormalities.

Conclusion: Vaccination of pregnant women against COVID-19 leads to a high level of immunity in pregnant women, i.e. 87%, leads to a 2.5-fold decrease in the incidence of coronavirus infection in mothers, 1.7 times in newborns, and also leads to a 1.8% decrease in complications associated with COVID-19 during pregnancy.

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INTRODUCTION

Coronavirus infection (COVID-19) is an acute infectious disease caused by a new strain of the virus that belongs to the category of coronaviruses [1,2,3]. In later times, there has been much prevalence of COVID-19 among pregnant women. The mortality rate from coronavirus infection among pregnant women is 27%. The increasing incidence of death in pregnant women suffering from COVID-19 is indicative of the extreme relevance of this problem[4,5,6]. In pregnant women with coronavirus, there is often a complication of pregnancy, which is: the inability to reach the term of pregnancy, the syndrome of the limitation of the delay in the growth of the fetus, the undesirable state of the fetus, and the increase in various indications for caesarean section[7,8,9]. In infants born from pregnant women suffering from coronavirus, the following neonatal complications are observed: fatal birth, neonatal death, low weight birth of children and asphyxiation of infants. Antenatal mortality of the fetus in women with coronavirus accounts for 2% [10,11,12]. There are various somatic diseases: chronic diseases of the lungs, including bronchial asthma, diseases of the cardiovascular system, arterial hypertension, diabetes,obesity, chronic kidney diseases and liver diseases, and pregnant women often constitute a group of at risk of severe COVID-19 disease [13,14,15].

An effective way to protect against coronavirus in pandemic conditions is to vaccinate against this disease, it is known that despite the fact that in the world there is a vaccine for pregnant women against many infectious diseases, unfortunately, vaccination against COVID-19 is carried out silently. It is known that only a mass vaccination against COVID-19 is capable of the formation of collective immunity among the population and protection against infectious diseases [16,17,18].

Potential immunoprophylaxis of COVID-19, especially in groups with a high risk of infection, including in pregnant women, is the body's ability to neutralize the fat agent, which in turn directly depends on the state of the human immune system of the pathogen of the infectious agent. Only, vaccination is the only effective way to control the spread of COVID-19 among pregnant women.

It is very important to take preventive measures to reduce the incidence and severe course of COVID-19 disease, as well as to prevent secondary complications in women entering the risk group, especially during pregnancy. Vaccination against COVID-19 can significantly reduce the incidence and mortality of pregnant women and their newborns. Currently, there is very little information about the vaccine against COVID-19 in pregnant women, and also specific recommendations for the vaccination of pregnant women against COVID-19 are being developed [19,20].

Today, there are a lot of unexplored features of

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vaccination of pregnant women against COVID-19 in Uzbekistan, there is insufficient data on the clinical and immunological safety of vaccines used in vaccination. For this reason, the issue of vaccination aimed at preventing infection of pregnant women with COVID-19 remains relevant. One of the most important functions of vaccination against COVID-19 during pregnancy is to increase the immune system in the female body, the antibodies that pass to the fetus and the babies that will be born. Thus, an assessment of the safety and effectiveness of vaccines administered against COVID-19 in pregnant women also requires further research. However, there has been a small number of studies aimed at studying the effect of the vaccine applied against SOVID-19 in pregnant women on the course of pregnancy, the antenatal development of the fetus, the activity of fetoplasentar Complex and the incidence of obstetric complications, which indicates the need to conduct a more extensive and in-depth study of this problem. In this regard, we decided to conduct this study aimed at determining the effectiveness and reactivity of the safety of vaccination of pregnant women against COVID-19. In this paper, the results of the study aimed at studying the clinical and laboratory characteristics of the vaccine against COVID-19 in pregnant women are presented. Also in this article, the issues of elimination of misconceptions and views of doctors against vaccination in the issue of vaccination of pregnant women are considered.

The aim of the study was to evaluate the safety, effectiveness, immunogenicity of vaccination in pregnant women who were vaccinated against COVID-19, as well as the results of pregnancy and childbirth.

RESEARCH MATERIALS AND METHODS

The study included 120 pregnant women who were vaccinated with the Gam-Covid-Vak vaccine against COVID-19. Of these, 60 pregnant women were vaccinated in the II trimester (I main group) and 60 were pregnant women were vaccinated in the II trimester (II main group), and the comparison group was pregnant women who refused 30 vaccinations. Vaccination in all women was conducted after receiving a letter of consent from them. Vaccination was conducted in 1 phase with a difference of 2 months. The vaccine was sent to a third of the shoulder socket in a dose of 0,5 ml. Clinical, immunological, hormonal, ultrasound, color Doppler karting, and statistical research methods were used in the study. The data obtained were processed by the method of statistical STATISTICA 10,0 program Epi Info 10.2.2 statistical program with the statistical package 7.2.0 and the detection of 2 data series errors interrelated between natural pairs by the method of Level correlation of Spirmen. Differences in P<0,05, P<0,01, P<0,001 were considered reliable.

RESULTS AND THEIR DISCUSSION

The reactivity, immunogenicity, and its effect on laboratory indicators and the state of the fetus and infants before vaccination and 1,2,3 months after vaccination were studied in pregnant women against COVID-19. It is worth noting that 70% of the pregnant women included in the study were women who had a predisposition to the complication of this pregnancy (the risk of miscarriage and premature birth, nausea of pregnant women, infestation of the fetus in the mother's womb and septic complications).The study, aimed at studying the reactivity of the vaccine in the early days of the post-vaccination period, found that no local and general reactions were observed strongly in any woman in whom the vaccine was administered, which indicates that the vaccine used was less allergenic and highly effective. A weak local reaction was observed in 28 (24%) of vaccinated women. From the general reactions: total dysfunction–75(62%) was observed in pregnant women, headache-27(22,5%) in women. In the period after receiving the 2–dose of the vaccine, weak pain in the lower abdomen, most often in women-12 (10%) pregnant women and diarrhea-6 (5%) pregnant women were observed.

According to laboratory research analysis, from the main biochemical markers lactatdigidrogeneza (LDG), alkaline phosphatase (AF), aspartataminotransferase (AST), alaninaminotransferase (ALT), creatinine, mochevina, total protein) before vaccination and during the post-vaccination period, the following results were obtained (r>0.05). In particular, it was found that in the first days after vaccination of pregnant women in the II and III trimesters, the amount of LDG was 234 IU /l and 233 IU /l respectively, the amount of if was 113 IU /l and 114 IU /l respectively, the amount of AST was 36 IU /l and 35 IU /l respectively, and the amount of Alt was slightly high.

In pregnant women vaccinated against COVID-19, an analysis of the characteristics of blood biochemical indicators in the period after vaccination was performed, an average increase in creatinine level in the early period after vaccination was recorded, and the duration of vaccination was 53,02 mkmol/l and 53,02 mkmol/l, respectively, r<0,05). However, the changes in all biochemical indicators observed in this study indicate that there are changes not only with the conducted vaccination, but also with the exact listed duration of pregnancy. Similar changes were observed in the control group of pregnant women.

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After vaccination, according to the results of a comprehensive assessment of the lipid profile (total cholesterin (TC), triglycerides (tg), low–density lipoproteids (LDL), high-density lipoproteids (HDL), atherogenicity index (AI) and very low-density lipoproteids (LDL) in dynamics, it was determined that there was a tendency to increase in all indicators included in the lipid profile in the control parameters taken for 1-month.

In particular, the total cholesterol level growth is from 4,13±0,31 mmol/l to 5,33±0,32 mmol/l in I-Group, in the II-in Group from 4,11±0,22 mmol/l. to 43±0,23 mmol/l was observed. In the control group, this indicator is from 3,46=0,21 mmol / l. to 5,53±0,25 mmol/l.

Along with UX, there was a tendency to increase in other indicators of lipid profile. TG quantity level I-in Group from 1,59±0,41 mmol / l. to 1,99±0,47 mmol/l growth, II-in Group from 1,53±0,21 mmol/l to 1,79±0,27 mmol/l growth was observed.

There was an increase in the amount of LDP and HDL, respectively 1,74±0,28 mmol/l and 1,77±0,01 mmol/l, 2,72±0,21 mmol/l and 2,77±0,25 mmol/l, while in the control group 4,69±0,21 mmol/l and 4,90±0,19 mmol/l (see table).

Table 1

Indicators of lipid profile in women undergoing the study, M±m

Indicators	I-group (n=60)	II- group (n=60)	Control group(n=30)
UX(mmol/l)	5,33±0,32	6,43±0,23	5,53±0,25
LDL(mmol/l)	1,74±0,28	2,77±0,25	4,90±0,19
LDL(mmol/l)	1,77±0,01	2,72±0,21	4,69±0,21
HDL (ммоль/л)	0,86±0,20	1,0±0,10*	1,01±0,13**
TG (mmol/l)	1,99±0,47	1,79±0,27*	1,54±0,21**
AI(IU)	6,28±0,44	3,58±0,37*	3,48±0,33**

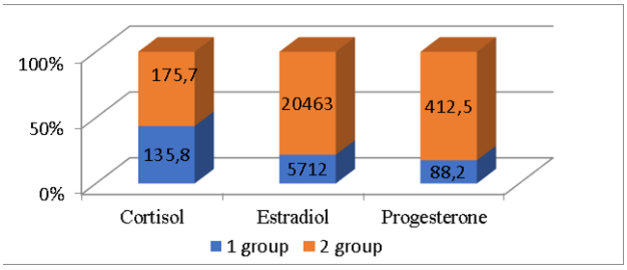
Note:
* – differences with respect to the control group are reliable (p<0,05); * *–differences with respect to the control and I– Group are reliable (p<0,05);** * –differences with respect to the control and I-II groups are reliable (p<0,05)

There was a very high increase in the AI Index in gurcs, and in these groups, respectively, 6,28±0,44 IU and 3,58±0,37 IU is (p<0,05). We found that the amount of HDL was slightly reduced compared to other indicators, and in groups, respectively, from 1,74±0,22 mmol/l to 0,86±0,20 mmol/l from up to 1,76±0,12 mmol/l. to 1,0±0,10 mmol/l decrease was observed.

Hormones analysis after conducted vaccination, the indicators of the amount of hormones in the comparison groups were found that intergroup index is almost significant, but the analysis corresponds to the period of pregnancy during which it is conducted (Figure 1).

The amount of progesterone hormone (88.2 and 412.5 ng/ml, respectively, according to the groups) and the amount of cortisol (135,8 and 175,7 nmol/l, respectively) increased accordingly, taking into account the increase in the duration of pregnancy in the comparison groups and accounted for the above-mentioned indicator. It was found that the most stable

indicator in the dynamics of observation belongs to the hormone estradiol (5712 and 20463pg / ml, respectively, in groups) and does not have significant changes in the values of comparison between groups and trimesters. No significant intergroup differences were found on all studied parameters(r<0.05).

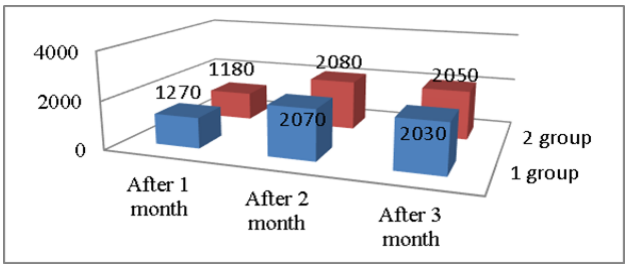


1-picture. Indicators of the amount of hormones in the blood of pregnant women after vaccination.

In order to determine the level of immunogenicity in pregnant women undergoing vaccination showed the presence of significant differences in the dynamics of titer level analysis of LGG immunoglobulins. In pregnant women vaccinated against COVID-19, a high level of LgG titer was observed after 1 month in Group I-1270 BAU/ml and in Group II - 1180 BAU/ml, r<0,05). When examined in 2 months after vaccination, the LGG titre was further increased compared to

the indicators after 1 month, respectively 2070 BAU/ml and 2080 BAU/ml in the groups (r<0,01). In vaccinated pregnant women, after 3 months, there was a slight decrease in the titer of LgG, and in the groups respectively 2030 BAU/ml and 2050 BAU/ml.

Titration indicators of LgG antibodies titration in relation to SARS-CoV-2 in the blood serum of pregnant women 1-2 months and after 3 months are given in Figure 2.



2-picture. Levels of LgG titer in vaccinated pregnant women, BAU/ml.

77 (64.2%) were detected in LgG 2050 BAU/ml titration in pregnant women, 13 (10.9%) were detected in pregnant women with 2070 BAU/ml titration, 14 (11.9%) were detected in pregnant women with 2080 BAU/ml titration.

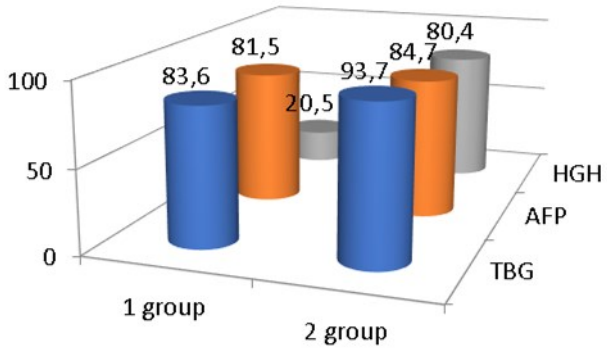
Thus, studies after vaccination revealed that in 104 (87%) of pregnant women who were vaccinated, the presence of LgG antibodies against SARS-Cov-2 was found.

In addition to these, we conducted a correlation analysis of the LgG titre level after vaccination and the duration of the vaccination and the number of vaccinations made, according to which it was found that the LgG titre level had an inverse correlation (r=-0,29) with respect to the duration after vaccination, and a direct correlation with the number of vaccinations made (r=0,29).

Analysis of the profile of cytokines in pregnant women undergoing vaccination revealed the presence of specific changes in the predisposition, determined by physiologic immunosuppression strains of the fetus: high levels of anti-inflammatory cytokines IL-1 (6,08 PG/ml and 16,4 PG/ml, respectively, in groups IL-10 (4,08 PG/ml and 14,2 PG, respectively, in groups), there was a significant Nevertheless, the proyallocation of the vector vaccine affected the production of cytokines: a short-term increase in the level of ifn-γ was most pronounced in pregnant women in the II trimester of pregnancy, and it composed 640tb, this can characterize the active participation in the immune response after vaccination.

In the III trimester of pregnancy, there was an increase in Il-4 production in the first month after vaccination. Indirect confirmation of this condition - the level of ifn-γ in Group I in the post-vaccination period formed 88 and manifested itself in the presence of a significant tuberculosis. The analysis of the profile of cytokines in groups showed that after vaccination in groups, the indicators slightly increased after a certain period of time, and these changes did not lead to instability of the immune system in pregnant women.

Markers characterizing the fetoplacental system in pregnant women vaccinated against COVID-19(TBG, AFP, XG), which showed that the main differences in these indicators are mainly in the indicator corresponding to the periods of pregnancy (3-picture).



3-picture. Dynamics of fetoplacentar complex markers in post-vaccination period

Thus, in women who were vaccinated in the second trimester of pregnancy, TBG was significantly lower than those who were vaccinated in the third trimester (r<0,001). As the direct correlation of the increase in the concentration of TBG to AFP(r<0,05) increased with the duration of pregnancy, there was an increase in the amount of this protein (r<0,001). In groups with indicators corresponding to the duration of pregnancy of the quantitative indicators of xG in vaccinated women, respectively, were 47000med/ml and 54000 MEd/ml (r<0.01). The more pronounced differences were 82,05+7,11 ng/ml and 93,17±5,27 ng/ml respectively in groups after the first dose of TBG vaccination and 120,12+3,11 ng/ml and 123,02+1,04 ng/ml after 2 doses (r<0,001). Analysis of the AFP level showed that in the II Group, the average level was 83,52+2,11 Me/ml) was 1,3 times lower than the level obtained 1 month after vaccination. A similar dynamics in the trimesters of pregnancy can be observed without significant differences with women vaccinated in the I Group.

According to ultrasound fetometry conducted in 22-24 and 28 weeks of pregnancy in pregnant women who received the vaccine, significant changes are detected in the main studied indicators. In the study of fetoplacentar complex, changes characteristic of the gestation period in the indicators of fetal development were noted. This condition is confirmed by the normal

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content of markers of fetoplacentar complex status in the II trimester of pregnancy. Fetoplacental dysfunction was detected in 5 (8,33%) women in I-Group. Differences in fetal development indicators were found during the study, which was conducted at 31-32 week against the background of a significant decrease in TBG in Group II.

Thus, this study, which was conducted to study the safety and effectiveness of vaccination of pregnant women against coronavirus infection, as well as the clinical laboratory characteristics after vaccination, showed that the vaccine against COVID-19 is safe and effective for the mother and fetus. Therefore, vaccination against coronavirus should be widely recommended to pregnant women, since its benefit is higher than the risk of catching an infection of COVID-19.

Thus, vaccination against coronavirus should be recommended to pregnant women who have diabetes, heart disease, obesity, kidney disease, bronchial asthma or mucovisidosis, chronic lung diseases, arterial hypertension, and liver diseases during pregnancy, as well as pregnant women with a high risk of infection with coronavirus. The optimal time for the use of vaccination in pregnant women is considered to be the II and III trimester of pregnancy, but in women with a high epidemiological risk and other concomitant diseases, or if there are risk factors, it is possible to carry out vaccination even in the I trimester of pregnancy.

CONCLUSION

Vaccination of pregnant women against COVID-19 leads to the formation of 87% immunity in pregnant women, the incidence of coronavirus is 2.5 times in mothers, 1.7 times in newborns, as well as a 1.8-fold decrease in the observed complications associated with COVID-19 in pregnancy.

CONFLICT OF INTERESTS. The authors declare no conflict of interest.

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