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Features State of the Fetoplacental System in Pregnant Women Vaccinated Against COVID-19

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Abstract **Purpose:** to study the features of the hormonal status and markers of the fetoplacental system in pregnant women after vaccination against COVID-19. **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, hormonal, ultrasound, Doppler and statistical research methods. **Results.** Analysis of the hormonal status and markers of the fetoplacental system in women vaccinated against COVID-19 did not reveal adverse changes in these indicators. All values established for all identified indicators were determined as corresponding to the gestational age, which did not lead to the occurrence of adverse events for them during pregnancy and in the fetus and infant. 2-3 months after vaccination, the level of the hormone estradiol in the blood increased 1.2 times compared to 1 month, and the hormone progesterone decreased 1.1 times. **Conclusion:** Vaccination of pregnant women against COVID-19 does not lead to significant fluctuations in the synthesis of placental hormones and markers of the fetoplacental complex in pregnant women vaccinated against coronavirus infection. 2-3 months after vaccination, the level of the hormone estradiol in the blood increased 1.2 times compared to 1 month, and the hormone progesterone decreased 1.1 times. The analysis of fetoplacental markers reveals changes in the duration of pregnancy after vaccination, and these changes do not adversely affect the fetus and labor activity.

Keywords Coronavirus infection, Pregnancy, Vaccine, Hormones, Fetoplacental markers

1. Introduction

In later times, the incidence of coronavirus infection among pregnant women has been increasing [1,2]. It is very important for pregnant women to take preventive measures to reduce the incidence and severe course of COVID-19 disease, as well as to prevent secondary complications during pregnancy [3,4]. An effective way to protect against coronavirus infection in pregnant women under pandemic conditions is to get vaccinated against this disease without saying it [5,6]. Only, vaccination is the only effective way to control the spread of COVID-19 among pregnant women [7,8]. Vaccination against COVID-19 can significantly reduce the incidence and mortality of pregnant women and their newborn infants [9,10]. It is well known that in many countries of the world, despite the fact that the vaccination of pregnant women against coronavirus is carried out on a large scale, studies aimed at studying the effect of vaccination against COVID-19 on the functioning of the fetoplacental system have been conducted with a very small number, therefore, it is necessary to conduct a wide range of research.

The purpose of the study was to investigate the effect of COVID-19 injection on the functioning of the fetoplacental system in pregnant women.

2. Material and Methods

The study included 120 pregnant women who were vaccinated against COVID-19, aged between 18 and 36 years of age. Of these, 60 were pregnant women who were vaccinated in the II trimester (I main group) and 60 were pregnant women who were vaccinated in the III trimester (II main group), while the comparison group was pregnant women who refused 30 vaccinations. All patients, conducted studies have matched the criteria for inclusion and no diseases associated with the inclusion criteria are clear. Criteria for inclusion: pregnant women aged 18-36 years of age, undergoing physiologic pregnancy, pregnant women in the II-III trimester for the duration of pregnancy and pregnant women who submitted a written consent letter to participation in the study were included. The criteria for non-inclusion in the study included oncological diseases,

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AIDS, hepatitis B and C infections in the Anamnesis, the last 3 months received immunoglobulin and blood preparations, the last 6 months immunomodulating drugs were used, cardiovascular and respiratory insufficiency, violations of liver and kidney function were detected, as well as fasting and metabolic disorders, acute infectious diseases, predisposition to allergic reactions. Vaccination was carried out in 1 phase with a difference of 2 months with the help of a Gam-Covid-Vak vaccine. The vaccine was injected into the deltoid muscle in a dose of 0.5 ml of one-third of the shoulder. Clinical, hormonal, ultrasound, Doppler and statistical research methods were used in the study. The amount of placental hormones was determined using the immunoferment method using standard reagents produced by firms “Boehringer Mannheim” (USA), “Beckman coulter” (USA), “DRG Diagnostics” (Germany) and Switzerland Hoffman La Roch using the MINDRAY MR-96A immunoanalyser.

Ethical Aspects. The study procedure doesn't interfere with any ethical basics and oral agreement was taken to all patients.

The obtained data was processed using the statistical package of software "Statistics 10.0".

3. Results and Discussion

The analysis of the level of the amount of hormones of the fetoplacental system, conducted in groups after vaccination, showed that after vaccination, the level of estriol in the blood serum of pregnant women increased with appropriate clarity in relation to the duration of pregnancy in vaccinated women in Group I, and in the examination conducted after 2 and 3 months, it was found that.Ni Made Up (P<0,01). A similar situation in the quantity indicators of the hormone Estriol was observed in pregnant women vaccinated in the II Group, in which the amount of this hormone in the 3rd month increased by 1.2 times compared to the indicators in the 1st Month, respectively by 6.8±4.01 ng/ml, by 7.4±3.12 ng/ml and by 8.6±12.1 ng/ml.

After vaccination of pregnant women, it was found that the level of the hormone of placental Lactogen increased by 1,1 times in vaccinated women in the I-group, with a corresponding increase in the duration of pregnancy, compared to the results obtained in studies 1-month after vaccination, and in groups, respectively, it was 6,8±2,01 mg/l, 7,4±10,01 mg/ A similar situation was observed in pregnant women who were vaccinated in Group II, both in women who were admitted to this group, the amount of the hormone of the placental Lactogen increased by 1.2 times compared to the indicator in the 3rd month, respectively, by 10,1±2,01 mg/l, 11,2±4,02 mg/l and 11,6±13,01 mg/l (p<0,01).

Analysis of the amount of progesterone hormone after vaccination against coronavirus, found that in women entering the I-Group, the amount of this hormone increased by 1,1 times compared with the period of pregnancy, that is, the initial, 1-month after vaccination, and in groups, respectively, 140,2±3,12 nmol/l, 148,9±3,13 nmol/l and 160,14±2,13 nmol/ The analysis of this hormone in pregnant women vaccinated in Group II found that the amount of progesterone hormone in them decreased by 1.2 times compared to the results obtained after 1-month period, respectively, 168,02±2,16 nmol/l, 155,12±4,02 nmol/l and 142,08±3,15 nmol/l compared to the months(p<0,01) (Table 1).

I-Group pregnant women who were vaccinated against COVID-19 found that the amount of cortisol hormone in the blood serum increased by 2.6 times compared with the duration of pregnancy, that is, 1-month after vaccination, and it was found to be 192,02±5,12 nmol/l, 272,02±8,05 nmol/l, and 502,03±7,12 nmol/l, respectively. A similar situation was observed in pregnant women vaccinated with II Group, in which the amount of the hormone cortisol increased by 1,0 times compared to the months, respectively 504,11±8,18 nmol/l, 506,01±6,15 nmol/l and 507,12±6,17 nmol/l (p<0,01) (1 table). In women in the I-Group vaccinated against coronavirus, the level of estradiol increased with respect to the duration of pregnancy, the indicator of 3 months after vaccination was found to have increased by 1.1 times compared to the indicator obtained after 1 month, and its amount was increased by 1561.04±1.03 PG/ml and 1628.05±1.06 pg/ml, respectively (p<0.01). A similar case was also observed in pregnant women vaccinated in II-Group, the amount of estradiol hormone 3 months after vaccination increased by 1.4 times compared to the 1-month follow-up, respectively 6520606±1.08 pg/ml, 8134,12±1.03 pg/ml and 9168,11±0.06 pg/ml (p<0.01).

Table 1. In women undergoing the study, the level indicators of the amount of fetoplacental komplex hormones in the blood serum during the post-vaccination period, M±m

Index	1-group n=60			2-group n=60		
	After 1 month	After 2 month	After 3 month	After 1 month	After 2 month	After 3 month
Estriol, ng/ml	2,8±12,1	4,4±11,02	6,4±10,1	6,8±4,01	7,4±3,12	8,6±12,1
Placental lactogen, mg/l	6,4±4,01	7,8±2,02	8,2±3,02	10,1±2,02	11,2±4,11	11,7±3,02
Progesterone nmol/l	140,2±3,12	148,9±3,13	160,14±2,13	168,02±2,76	155,12±4,02	142,08±3,15
Cortisol, nmol/l	192,02±5,12	272,02±8,05	502,03±7,12	504,11±8,18	506,01±6,15	507,12±6,17
Estradiol pg/ml	1561,04±1,03	1628,05±1,06	1780,6±1,02	6525,06±1,08	8134,12±1,03	9168,11±0,06

Note: ** reliable in relation to the indicators after 1 month(r<0,001); ***-3 reliable in relation to the indicators in the month (p<0,05).

Thus, according to the dynamics of follow-up after vaccination, studies aimed at studying the status of hormones of the fetoplacental system, changes in the level of the amount of hormones of the fetoplacental system were found only in indicative values specific to the duration of pregnancy, and no negative changes were observed in the values of the comparison between the groups and the trimesters (p<0,05).

We also conducted an analysis of the correlation dependence of the level of the amount of hormones in these groups on the duration after vaccination and the number of vaccinations, as well as on the duration of pregnancy, according to which the level of the estradiol hormone in the blood of vaccinated pregnant women is directly related to the presence of strong correlation identified, the correlation coefficient was (r=-0,29) (p<0,05) (**Fig. 1**).

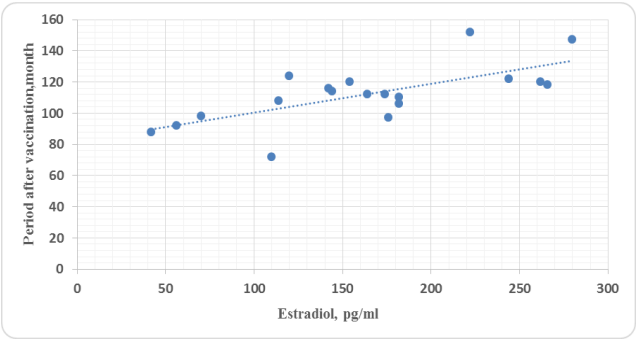

Figure 1. Pregnant women who are vaccinated against COVID-19 have a correlation between the amount of estradiol hormone in the blood serum and the duration of pregnancy, the number and duration of vaccinations

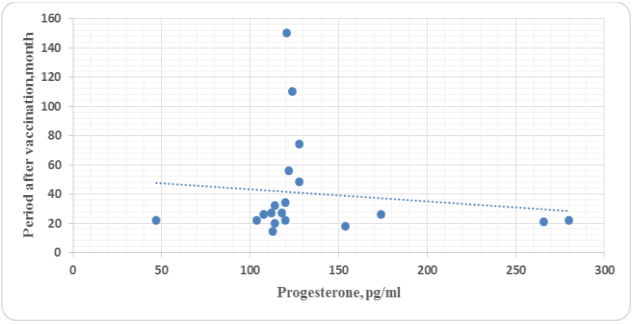

Figure 2. The correlation between the duration of pregnancy, the number and duration of vaccinations with the level of progesterone hormone in the blood serum of pregnant women vaccinated against COVID-19

The level of the amount of progesterone hormone in the blood of vaccinated pregnant women was determined by the presence of an inverse weak correlation coefficient (r=-0,07) with respect to the duration of pregnancy after vaccination, and with respect to the duration and number of vaccination, there was a direct correlation coefficient (r=-0,17) (p<0.05) (**Fig. 2**).

The level of the amount of the hormone cortisol in the blood of vaccinated pregnant women was determined by the presence of a strong correlation coefficient (r=0,29) directly with respect to the duration of pregnancy after vaccination, and with respect to the duration and number of vaccination, there is a weak negative correlation coefficient (r=-0,29) (p<0,05) (**Fig. 3**).

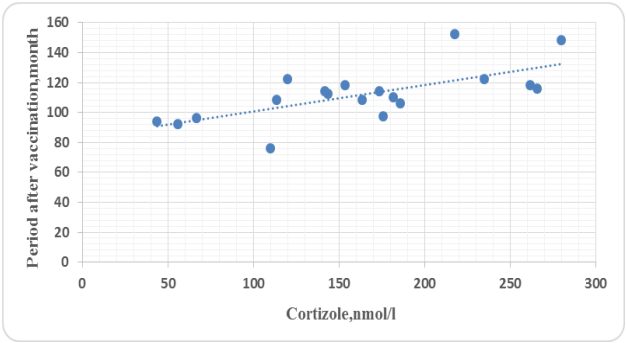

Figure 3. Pregnant women who are vaccinated against COVID-19 have a correlation between the amount of the hormone cortisol in the blood serum and the duration of pregnancy, the number and duration of vaccinations

Apart from these, we also conducted a value levels analysis of the markers of the fetoplacental system in pregnant women vaccinated against COVID-19: trofoblastic glycoprotein (TBG), alfafetoprotein (AFP), chorionic gonadotropin (CG).

According to the results of the analysis, it was found that the amount of TBG after 1 month of vaccination in pregnant women vaccinated in 1-group was 2,2 times lower than in vaccinated women in 2-Group, respectively in the groups was 35008,04±12,6 ng/ml and 800802±11,02 ng/ml (p<0,001). However, it was observed that in pregnant women who were vaccinated in 1-group, there was an increase in the number of times compared to the indicators after 1-month after vaccination in 2 and 3 months, respectively, 35008.04±12.06 ng/ml, 55048.02±1.02 ng/ml and 120018.2±1.04 ng/ml, respectively.

A similar situation was observed, namely, an increase in this hormone, in vaccinated women of II-Group, and these indicators increased by 1.7 times compared to the months, respectively, by 8008.02±11.02 ng/ml, by 95054.01±1.04 ng/ml and by 140018.1±1.02.6.

Table 2. In women undergoing the study, the level indicators of the amount of fetoplacentareksex markers in the blood serum during the post-vaccination period, M±m

Index	1-group n=60			2-group n=60		
	After 1 month	After 2 month	After 3 month	After 1 month	After 2 month	After 3 month
TBG, ng/ml	35008,04±12,6	55048,02±1,02	120018,2±1,04	80008,02±11,02	95054,01±1,04	140018,01±1,02
AFP, ME/ml	78,03±6,12	88,52±2,01	130,34±13,02	150,04±10,6	176,28±2,37	215,24±7,22
HCG, CG/ml	2740,23±3,10	3270,14±3,06	5420,12±6,12	6236,12±3,04	7013,04±2,06	78041,05±1,03

Note: ** reliable for indicators after 1 month(p<0,001);
***-3 is more reliable than the indicators in the months (p<0,05)

In I-Group pregnant women vaccinated against COVID-19, it was found that the amount of alfafetoprotein (AFP) in the blood serum was 1,6 times lower than the amount indicators after vaccination, 2 and 3 months after vaccination, respectively, 78,03±6,12 me/ml and 88,52±2,01 ME/ml and 130,34±13,02 ME/ml (p<0,001). A similar situation was observed in pregnant women of the II Group vaccinated against coronavirus and increased by 1.4 times compared to the months, respectively made 150404±10,6 ME/ml, 176,28±2,37 ME/ml and 215,24±7,22 ME/ml. After vaccination in pregnant women who were vaccinated against COVID-19, the analysis of the quantitative level of chorionic gonadotropin (HG) showed that in both groups of pregnant women, this marker decreased in quantity levels as the gestation period increased. In particular, we observed that HG in I group women increased by 1.9 times compared to the indicators after 1 month after vaccination, 2 and 3 months, and in these months, respectively, 2742323±3,1 ME/ml and 3270,14±3,06 me/ml, as well as 5420,12±6,12 ME/ml, and in women vaccinated in II Group, this marker ME/ml and 7013,04±2,06 ME/ml as well as 78044,05±1,03 ME/ml. (Table 2).

Thus, in women who were vaccinated in the second trimester of pregnancy, TBG was detected significantly lower incidence of pregnancy than in women who were vaccinated in the third trimester, namely 2.2 marotaba (p<0,001). An increase in the concentration of AFP and TBG and an increase in the level of HG corresponding to the duration of pregnancy were directly related to the duration of pregnancy, that is, as the duration of pregnancy increased, there was an increase in the amount of them (p<0,001).

Thus, the study, which was conducted to investigate the activity of the fetoplacental system in women who were vaccinated against COVID-19, found that this system is negative changes in the hormonal and FPK markers, which in turn indicates that the vaccination against COVID-19 in pregnant women is absolutely harmless.

4. Conclusions

Vaccination of pregnant women against COVID-19 does not lead to negative changes in the synthesis and quantitative indicators of hormones of the fetoplacental system. After 2 and 3 months after vaccination, the content of the hormone estradiol in the blood increases by 1.2 times compared to 1 month after vaccination, and the hormone progesterone decreases by 1.1 times. The study of the correlation between the frequency of vaccinations, the duration of pregnancy and the content of hormones in the blood showed the presence of a direct correlation between the hormone estradiol and an inverse correlation with the hormone progesterone.

Conflict of interests. The authors declare no conflict of interest.

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