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## TREATMENT OF PREGNANT WOMEN INFECTED WITH SYPHILIS WITH INTRAVENOUS PENICILLIN G: PHARMACOKINETICAL AND CLINICAL STUDY

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### SUMMARY

Treatment of pregnant women infected with syphilis with intravenous infusions of penicillin G (2 million units every 12 hours) favors higher concentration of penicillin in blood serum (31 vs. 6-11 mkg/ml) and lower frequency and intensity of adverse effects (2.5 vs. 5.6%) in comparison with intramuscularly injections of benzyl penicillin (0.5–1.0 million units every 3 hours). Penicillin G favored a faster regress of clinical manifestations of syphilis (4-12 vs. 7-17 days) earlier obtaining negative results of serologic tests, more favorable outcomes of pregnancy if compared to group of patients who received benzyl penicillin. Thus, penicillin G is quite an effective medicine for treatment of pregnant women infected with syphilis.

**KEY WORDS:** syphilis, pregnancy, treatment, penicillin G, pharmacokinetics, and clinics

### INTRODUCTION

The problem of syphilitic infection in pregnant women has become pressing in Eastern Europe and in Ukraine recently [1,2,3]. Inadequate and untimely treatment contributes to the risk of congenital syphilis in their children [3,4]. Treatment syphilis in Ukraine is strictly determined by special Guidelines [5]. Existing methods of treating pregnant women infected with syphilis have considerable drawbacks like, for example, the necessity of administering penicillin eight times every 24 hours, which contributes to growing sensitization of the mother's and fetus's organisms [6]. That is why it has become absolutely necessary to develop new methods of specific therapy for syphilitic infection in pregnant women with application of a new generation of preparations from penicillin family. The aim of the present work was to devise a new method of treatment of pregnant women infected with syphilis with penicillin G taking into consideration clinic, serologic features of the disease and pharmacotherapeutic features of this medicine.

### MATERIALS AND METHODS

153 pregnant women (aged 16-45) infected with syphilis were observed and treated from 1996 till 1999. An independent «Ethic committee

**Group 2 (72 patients)** was administered to intramuscular injections of 1,000,000 units of sodium salt of benzylpenicillin every 3 hours without night breaks.

of the Health Ministry of Ukraine» approved the trial. Informed, written consent had been obtained from all the patients before they participated in the study. The 153 women were divided into 3 groups according to the type of therapy they were administered to.

**Group 1 (40 patients)** was administered to penicillin G and benzatinpenicillin. Penicillin G (crystalline, sodium salt) was administered intravenously twice a day, 2 million units every 12 hours. Half an hour before the first injection in penicillin G, an intramuscular injection on prednisolone (30 ng) was administered to the patients. The period of treatment was equal 10 days in case of primary syphilis; to 12 day in case of secondary and early latent syphilis if the patient had been infected for less than 6 months; to 14 days in case of secondary and early latent syphilis if the patient had been infected for more than 6 months. In case of late latent, and latent non-confirmed syphilis (when the duration of infection was unknown) the treatment consisted of 2 periods (each of them lasted 14 days). The second period of treatment was carried out 3-4 weeks after the first one. Irrespective of the form of syphilis, one intramuscular injection of 2,400,000 units of benzatinpenicillin G was administered (1,200,000 units into each buttock) to the patients 12 hours after the last penicillin G injection.

**Group 3 (41 patients)** was with intramuscular injections of 500,000 units of benzylpenicillin every 3 hours without night breaks.

According to the direction of the Health Ministry of Ukraine Guidelines [5], and depend-

ing from the form of syphilis, the main course of treatment in Groups 2 and 3 lasted 12 days in cases of primary syphilis, 14 days in cases of fresh secondary syphilis, 18 days in cases of secondary recurrent syphilis, 18 days in cases of early latent syphilis. In cases, of late latent syphilis 2 courses of 18 days each were administered with an interval of 1.5 months.

Concentration of penicillin in blood serum was determined with the help of the method of high performance liquid chromatography. The samples for the investigations were prepared, extracted and purified according to *Boatto G.* and his co-authors and modified in our laboratory [7]. The concentrating cartridge DIAPACK C16 and BECKMAN chromatograph with the CENAPON SCX C18 4x18 frame were used at the wavelength of 230 nm. The results were treated with the help of the PC program SYSTEM GOLD HPLC-P/ACE. The following pharmacokinetical values were determined: C<sub>max</sub> – the maximum concentration in blood serum; T<sub>max</sub> – the time of gaining the maximum concentration; C<sub>m</sub> – the average concentration in blood serum within the period of observation; T<sub>1/2</sub> – the half-life period, i.e. the time within which the concentration drops by 2 times; areas under curves (AUC), i.e. the surface of areas under curves of dependence of the concentration from time. The weight dose of the administered matter was calculated proceed-

ing from the fact that 1 acting unit of penicillin (of penicillin G) contains 0,5988 mkg of active matter.

The statistic treatment of the results was carried out with the help of the standard software package of Microsoft Office'97. Mean values in samples were compared with the help of *Student's t-test, nonparametric sign-test, Craskell-Wolles H-test, median test, and Freedman rank sum* [8]. Quantitative evaluation of achieving of negative results of serologic tests (negativation) was carried out with the application of *Kaplan-Meier* statistical analysis. The calculations were done with the help of SPSS 9.0 computer program. The reliability level was estimated as equal to 95%.

## RESULTS AND DISCUSSION

The distribution of the patients according to their age, term of pregnancy at which the patient was treated, associated pathology, syphilis diagnosis structure and results of serologic tests before treatment are represented in Table 1. The three groups of patients did not differ in a significant way according to their clinical and epidemiological features. This fact lets us compare the treatment results of each group with the results of the other groups.

**Table 1**  
Distribution of patients according to age, term of pregnancy, associated pathology, diagnosis and results of serologic tests before treatment

Features	Groups*			Total (n=153)
	1 (n=40)	2 (n=72)	3 (n=41)	
Mean age (years)	22,9	22,8	23,4	23,0
Mean term of pregnancy (weeks)	22,8	19,4	20,4	20,9
Obstetric pathology (%)	18 (45%)	43 (60%)	12 (29%)	73 (48%)
Gynecologic pathology (%)	17 (43%)	23 (32%)	7(17%)	47 (31%)
Associated pathology (%)	30 (76%)	47 (65%)	25 (61%)	102 (67%)
Primary syphilis (%)	1 (2,5%)	3 (4%)	0 (0%)	4 (3%)
Secondary syphilis (%)	6 (15%)	16 (22%)	7 (17%)	29 (19%)
Latent early syphilis (%)	27 (68%)	44 (61%)	25 (61%)	96 (63%)
Latent late syphilis (%)	6 (15%)	9 (12,5%)	9 (22%)	24(16%)
Mean geometric titers of CFT• antibodies	1:12,0	1:13,1	1:10,9	1:12,0

\* The three groups of patients did not differ statistically for all features (P>0,05)  
• Complement fixation test

Penicillin concentration was determined in blood serum of 15 pregnant women infected with syphilis at the term of pregnancy of 25-30 weeks (5 patients from each group). Blood was taken 0.5, 1, 3, 6, 12, 24, 48 hours after the beginning of treatment. The average value of penicillin concentration in blood serum in the compared group is represented on Fig. 1. According to Fig.1, in case of intravenous injection of penicillin G a high concentration of penicillin in blood serum is

gained within 0.5-1 hour after the injection. This concentration is 3 times as high as in case of intramuscular injection of 1 million units of penicillin and 5 times as high as in case of administering 500,000 units. This concentration exceeds the necessary minimal level (0.2 mkg/ml or 0.3-0.4 units/ml) by 100 times [6,9]. Fast generation of high penicillin concentration in blood serum is essential for saturation of tissues (and first of all of nerve tissues) with penicillin and for penetra-

tion of its therapeutic concentrations through the placental barrier. A relatively high penicillin concentration was preserved for 12 hours in Group 1. By the following infusion it was equal to 5 mkg/ml on the average and exceeded the necessary minimal level by 20-30 times. In group 2 penicillin concentration was equal to 3.5 mkg/ml on the average by the time of the following injection (in three hours) and exceeded the necessary minimal level by 15 times. In group 3 penicillin concentration was lower and equal to 2 mkg/ml, but still it was sufficient. It exceeded the necessary minimal level by 10 times.

The major pharmacokinetical parameters (the mean values for the compared groups) of determining penicillin concentration in blood of pa-

tients from Groups 1, 2, 3 are represented in Table 2. The maximum penicillin concentration in blood serum (irrespective of time of its generation) in Group 1 was 3 times as high as it was in Group 2 and 5 times as high as it was in group 3. The average penicillin concentration in blood serum within the observation period (48 hours) differed as well. In Group 1 it was 2.4 times as high as in Group 2 and 4 times as high as in Group 3. The half-reduction period for penicillin G (in case of intravenous injection of 2 million units) lasted for approximately 3 hours, while for benzyl penicillin it lasted for 1.5 hours. In case of treatment method №.1 the surface of areas under the curve 'concentration-time' exceeded the AUC in method №.2 by 2.4 times and in method №.3 by 4.1.

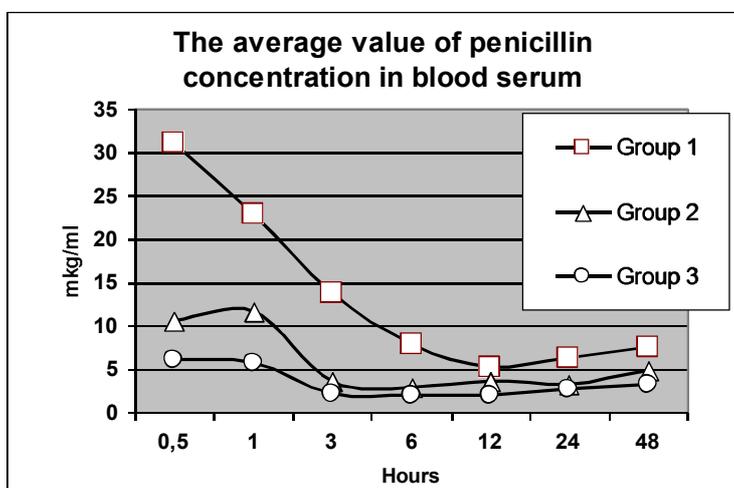


Fig. 1. The average value of penicillin concentration (mkg/ml) in blood serum in the compared groups. **Group 1** - Penicillin G intravenously twice a day, 2 million units every 12 hours; **group 2** - benzyl penicillin intramuscularly, 1 million units, every 3 hours; **group 3** - benzyl penicillin intramuscularly, 0.5 million units, every 3 hours

**Table 2**  
The major pharmacokinetical parameters (the mean values for the compared groups 1, 2, 3)

Pharmacokinetical parameters	Group 1 Penicillin G intravenously twice a day, 2 million units every 12 hours	Group 2 Benzyl penicillin intramuscularly, 1 million units, every 3 hours	Group 3 Benzyl penicillin intramuscularly, 0.5 million units, every 3 hours
Cmax – maximum concentration in blood serum (mkg/ml)	31,0	11,6	6,1
Cm –the mean concentration in blood serum (mkg/ml)	13,2±3,8	5,6±1,4	3,3±0,7
T1/2 – half-life period (hours)	3,1	1,2	1,4
AUC - Areas under curves (mkg/ml) * hour	92,3	38,9	22,8

Thus, a high level of penicillin concentration in blood serum is generated by means of treating pregnant women infected with syphilis with intravenous infusions of penicillin G. Its necessary level is preserved within 12 hours. The obtained

data demonstrate satisfactory efficiency of all the three investigated methods. However, method №.1 is preferable because a higher level of saturation of tissues with penicillin is gained with fewer injections a day.

The following features were compared in order to give clinical evaluation of the investigated methods: tolerance of treatment (toxic and allergic effects, exacerbation reaction of Yarish-Lukashevich-Herksheimer), immediate results of treatment – dynamics of reduction of skin and mucous rash within the period of treatment; distant results (dynamics) of negativation of the standard complex of serologic tests and the outcome of pregnancy and labours both for the mother and the foetus.

Apart from clinical effectiveness, tolerance of treatment is an essential factor determining the choice of treatment tactics. This is particularly important for treatment of pregnant women because their organisms are especially sensitive to toxic and allergic drug effects. We understand the notion of tolerance of treatment as both patients' subjective feelings and objective manifestations

of adverse tests to a medicine. The data on tolerance of the three compared methods are summarized in Table 3.

Adverse tests connected with allergic and toxic effects of the medicines as well as exacerbation tests were less frequent and intensive in case of the first method than in the second and third ones. In Group 1 the highly purified preparation of penicillin – penicillin G – was administered intravenously. Before the beginning of treatment an intramuscular injection of prednisolone (30 mg) was administered to the patients 0.5 hour before the first injection of penicillin G. It is assumed that these two factors would favour the tolerance of treatment for the patients from Group 1.

A comparison of regress terms for siphylids was carried out for patients infected with active forms of syphilis in the observed cases (Table 4).

Table 3

**Adverse allergic and toxic effects of the medicines and exacerbation reaction (the number of cases and the percent for the compared groups 1,2,3)**

Adverse reactions*	Group 1 Penicillin G intravenously twice a day, 2 million units every 12 hours		Group 2 Benzyl penicillin intramuscularly, 1 million units, every 3 hours		Group 3 Benzyl penicillin intramuscularly, 0,5 million units, every 3 hours	
	№	%	№	%	№	%
<b>Allergic and toxic effects:</b> General weakness, headache, urticary & nodular rash, itch of genitalia, pain in the bottom of a abdomen, palpitation	1	2,5	4	5,6	3	7,3
<b>Herxheimer reaction:</b> Temperature rise (up to 39C), chilling, general weakness, headache, exacerbation of roseola	7	17,5	21	29,2	11	26,8

\* For all refetions Group 1 differed statistically Groups 2 and 3 (P<0,05)

Table 4

**A comparison of regress terms for syphilis (the mean values for the compared groups 1,2,3).**

Clinical fatures*	Group 1 Penicillin G intravenously twice a day, 2 million units every 12 hours	Group 2 Benzyl penicillin intramuscularly, 1 million units, every 3 hours	Group 3 Benzyl penicillin intramuscularly, 0,5 million units, every 3 hours
Hard chancres	7,0±1,2	10,5±3,2	10,5±1,6
Lymphadenitis	12,0±3,1	15,3±2,2	17,5±1,8
Papules	57,0±2,1	13,2±1,6	16,7±2,5
Roseolae	4,5±0,	7,5±2,5	7,0±0,0

\* For all features Groups 1 differed statistically from Groups 2 and 3 (P<0,05).

Hard chancres in the main Group 1 were absorbed upon average 3-4 days earlier than in Groups of comparison 2 and 3; lymphadenitis was over 3-6 days earlier; roseola was over 2 day:101

Thus, intravenous injections of 2,000,000 units of penicillin G every 12 hours favoured a faster regress of clinical manifestations of early syphilis in pregnant women in comparison with

earlier. Papules were absorbed upon the average 4 days earlier.

administering 500,000 and 1,000,000 units of benzylpenicillin intramuscularly every 3 hours.

Kaplan-Meier analysis seems to be the most reliable for statistical evaluation of treatment ef-

fectiveness within the compared groups on the basis of analyzing the time necessary for recovery (in this case, for receiving negative results of serologic tests). The data on the negatigation of serologic tests are summarized in Table 5. 3 months after the treatment the results of Wassermann test were negative in Group 1 about 1.8 times more often than in Group 2 and 3.8 times more often than in Group 3 (27.5%, 15.5% and 7.3% respectively). The hazard ratio that reflects the number of negative results within the groups 3 months after the treatment is equal to **1.9** for Groups 1 (0.3216) and 2 (0.1683), while for Groups 1 (0.3216) and 3 (0.076) it is equal to **4.2**. In 6 months of observation the frequency of gaining negative results of Wassermann test differed in the following way: by 1.7 times between Groups 1 and 2, and by 2.2 times between Groups 1 and 3. The hazard ratio was equal to **2.1** and **2.7** re-

spectively. 9 months later the number of negative results in Group 1 was 1.3 times bigger than in Group 2, and 1.7 times higher than in Group 3.

The hazard ratio was equal to **1.5** and **2.3** respectively. 12 months later the number of negative results between Groups 1 and 2 and 1 and 3 did not essentially differ – by 4-5%. The hazard ratio was not significant either and equaled **1.3** and **1.2**. Consequently, by the end of the observation period the differences as to the frequency of negative results of Wassermann test become practically leveled. *Breslow* and *Tarone-Ware* statistical tests (which are designed to determine differences in distribution of gained negative results of Wassermann test depending on the treatment factor) have demonstrated that the differences between the compared groups are reliable (B=8.67, P=0.0131, TW=7.46; P=0.024).

**Table 5**

**The data on the negatigation of serologic tests, each 3 months within 1 year of observations (analysis Kaplan-Meier)**

Month	Group 1 Penicillin G intravenously twice a day, 2 million units every 12 hours			Group 2 Benzyl penicillin intramus- cularly, 1 million units, eve- ry 3 hours			Group 3- Benzyl penicillin intramuscularly, 0,5 million units, every 3 hours		
	№	%±p%	Hz	№	%±p%	Hz	№	%±p%	Hz
Wassermann test									
3	11	27,5±0,7	0,3216	11	15,5±0,4	0,1683	3	7,3±0,4	0,076
6	23	57,5±0,8	0,8557	24	33,8±0,6	0,4125	11	26,8±0,7	0,3124
9	27	67,5±0,7	1,1239	38	53,5±0,6	0,7662	16	39,0±0,8	0,4947
12	35	87,5±0,5	2,0794	58	81,7±0,5	1,6977	34	82,9±0,6	1,7677
Micro test of precipitation									
3	12	30,0±0,7	0,3567	9	12,7±0,4	0,1356	3	7,3±0,4	0,076
6	21	52,5±0,8	0,7444	22	31,0±0,6	0,3709	13	31,7±0,7	0,3814
9	24	60,0±0,5	0,9163	36	50,2±0,6	0,7073	18	43,9±0,8	0,5781
12	37	92,5±0,4	2,5903	63	88,7±0,4	2,1832	29	70,7±0,7	1,2287

1 - Amount of patients, in witch serologic tests has become negativ to the given term

2 - Percentage of patientes, in which serologic tests has become negativ to the given term ± standard error

3 - Hazard coefficient reflects a degree negative tests to the given term

The analysis of negatigation of results of micro test of precipitation has demonstrated in general the same situation (Table 5). Three months after the treatment negative results of micro test of precipitation were gained in Group 1 2.4 times as often as in Group 2, and 4.1 times as often as in Group 3 (30.0%, 12.7% and 7.3% respectively). The hazard ratio that reflects the number of negative results within the groups 3 months after the treatment was equal to **2.6** for Groups 1 (0.3567) and 2 (0.1356) and to **4.7** for Groups 1 (0.3567) and 3 (0.076). In 6 months of observation the frequency of gaining negative results of micro test of precipitation in Groups 1 and 3 were still noticeable (it was 1.3 higher in Group 1 than in Group 2), while the hazard ratio was equal to 2.1.

micro test of precipitation differed in the following way: by 1.7 times between both Groups 1 and 2, and Groups 1 and 3. Thus, the hazard ratio was equal to **2.0**. 9 months later the number of negative results of micro test of precipitation in Group 1 was 1.2 times bigger than in Group 2, and 1.4 times higher than in Group 3. The hazard ratio was equal to **1.3** and **1.6** respectively. 12 months later the number of negative results between Groups 1 and 2, 1 and 3 did not essentially differ – by 3.8%. The hazard ratio was not significant either and equaled **1.2**. By the end of the observation period (12 months after the treatment) the differences as to the frequency of negative results of micro test of precipitation in Groups 1 and 3 were still noticeable (it was 1.3 higher in Group 1 than in Group 2), while the hazard ratio was equal to 2.1. The statistical *Breslow* test has demonstrated that the differences between the compared groups as to distribution of negative results are reliable (B=6.48, P=0.0392). *Taron-Ware* test has demonstrated that differences in distribution of negative

results of micro test of precipitation according to the administered treatment approach the credibility level of 95% (TW=5.42; P=0.0665).

Thus, negative results of the standard complex of serologic tests in case of the patients who received penicillin G are obtained earlier than in case of the patients who were administered to benzylpenicillin sodium salt. Especially essential

discrepancies take place within the first 6 months following the treatment period. This gives evidence to the fact that the offered method of treatment favours obtaining negative results earlier.

The efficiency of treatment was evaluated according to outcomes of pregnancy in the 3 compared groups (Table 6).

**Table 6**

**Outcomes of pregnancy in the three compared groups**

Outcome	Group 1		Group 2		Group 3	
	Penicillin G intravenously twice a day, 2 million units every 12 hours		Benzyl penicillin intramuscularly, 1 million units, every 3 hours		Benzyl penicillin intramuscularly, 0,5 million units, every 3 hours	
	№	%	№	%	№	%
Labours*	26	65,0	39	54,2	17	41,5
Abortion	9	22,5	18	25,0	14	34,1
Induced labours**	0	0	3	4,2	2	4,9
Stillborn	2	5,0	8	11,1	5	12,2
Unknown	3	7,5	4	5,6	3	7,3

\* Group 1 differed statistically from Group 3 (P<0,05).

\*\* Group 1 differed statistically from Group 2 and 3 (P<0,05).

Labours were the outcome of pregnancy for a higher percentage of patients in Group 1 than in Groups 2 and 3. The differences as to this rate between Groups 1 and 3 are reliable (t=2.14; P=0.0357). The difference as to the percentage of induced labours was also reliable between Groups 1 and 2 (t=2.094; P=0.0385) and between Groups 1 and 3 (t=2.007; P=0.0482). Stillborn was observed in 4.9±3.4% cases in Group 3 and was not observed in Groups 1 and 2.

Thus, the outcomes of pregnancy in the group of patients who were administered to 2 million units of penicillin G every 12 hours are more favourable than for the patients from Groups 2 and 3 who received benzylpenicillin.

**CONCLUSION**

The examination of immediate and late results of treatment administered to 153 pregnant women infected with syphilis according to the method of treatment has proved that:

- treatment of pregnant women infected with syphilis with intravenous infusions of penicillin G favours high concentration of penicillin in blood serum; penicillin G penetrates into tissues easily and is preserved in them for a long time;

- frequency and intensity of adverse tests con- 103

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nected with allergic and toxic medicine effect as well as of Yarish-Lukashevich-Herksheimer test in case of administering penicillin G in combination with 30 mg of prednisolone were lower than in case of administering benzylpenicillin;

- intravenous infusion of penicillin G favoured a faster regress of clinical manifestations of syphilis in pregnant women infected with syphilis if compared to administering benzylpenicillin;
- negative results of the standard complex of serologic tests in case of the patients who received penicillin G are obtained earlier than in case of the patients who were administered to benzylpenicillin;
- the outcomes of pregnancy in the group of patients who were administered to penicillin G are more favourable than for the patients from who received benzylpenicillin.

Thus, the obtained data give evidence to the fact that application of penicillin G as a specific antisiphilitic medicine is quite an effective method of treatment of pregnant women infected with syphilis

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## **ЛІКУВАННЯ ВАГІТНИХ ЖІНОК, ХВОРИХ НА СИФІЛІС, ПЕНІЦИЛІНОМ G (ВОІСНЕМІЕ)**

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### **РЕЗЮМЕ**

Метою даної роботи було вивчити ефективність лікування вагітних, хворих сифілісом, пеніциліном G (ВОІСНЕМІЕ) 2 млн. ОД в/в два рази на добу 14 днів. Найближчі і віддалені результати лікування вивчені у 153 хворих у залежності від методу лікування. Показано, що при лікуванні внутрішньовенними інфузіями пеніциліну G (ВОІСНЕМІЕ) у сироватці крові створюється висока концентрація пеніциліну. Частота й інтенсивність алергійних і токсичних побічних реакцій при застосуванні пеніциліну G (ВОІСНЕМІЕ) були нижче, ніж при застосуванні бензилпеніциліну. Спостерігався більш швидкий регрес клінічних проявів сифілісу. Негативація стандартного комплексу серологічних реакцій відбувалася швидше. Результати вагітності більш сприятливі. Таким чином, отримані результати свідчать про високу ефективність методу лікування вагітних жінок, хворих сифілісом, використанням пеніциліну G (ВОІСНЕМІЕ) як специфічного протисифілітичного засобу.

**КЛЮЧОВІ СЛОВА:** сифіліс, вагітність, лікування, пеніцилін G, фармакокінетика, клініка

## **ЛЕЧЕНИЕ БЕРЕМЕННЫХ ЖЕНЩИН, БОЛЬНЫХ СИФИЛИСОМ, ПЕНИЦИЛЛИНОМ G (ВОІСНЕМІЕ)**

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### **РЕЗЮМЕ**

Целью данной работы было изучить эффективность лечения беременных, больных сифилисом, пенициллином G (ВОІСНЕМІЕ) 2 млн. ЕД в/в два раза в сутки 14 дней. Ближайшие и отдаленные результаты лечения изучены у 153 больных в зависимости от метода лечения. Показано, что при лечении внутривенными инфузиями пенициллина G (ВОІСНЕМІЕ) в сыворотке крови создается высокая концентрация пенициллина. Частота и интенсивность аллергических и токсических побочных реакций при применении пенициллина G (ВОІСНЕМІЕ) были ниже, чем при применении бензилпенициллина. Наблюдался более быстрый регресс клинических проявлений сифилиса. Негативация стандартного комплекса серологических реакций происходила быстрее. Исходы беременности более благоприятные. Таким образом, полученные результаты свидетельствуют о высокой эффективности метода лечения беременных женщин, больных сифилисом использованием пенициллина G (ВОІСНЕМІЕ) в качестве специфического противосифилитического средства.

**КЛЮЧЕВЫЕ СЛОВА:** сифилис, беременность, лечение, пенициллин G, фармакокинетика, клиника