Evaluation, efficacy and tolerability of GlucoNovax tablet in type 2 diabetic patients

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Abstract: Type 2 diabetes mellitus (T2D) is a chronic metabolic disease regarded as insulin resistance and progressive failure of β cells. Beta cells secretagogues are useful to reach satisfactory glycemic control. Glimepiride is a second-generation sulfonylurea excites pancreatic beta cells to discharge insulin. Glimepiride may be safer to use in patients with cardiovascular disease due to lack of destructive effects on ischemic preconditioning. It is effective in dropping fasting plasma glucose (FPG), postprandial glucose and glycated hemoglobin levels and is a useful and cost-effective option treatment for the management of T2D. Total 40 patients were selected from OPD setting at RSNPMTS Endocrinology center Ministry of Health Republic of Uzbekistan, and corresponding to criteria for inclusion / exclusion. 10 patients with T2D switched from receiving other forms of Glimepiride (Amaryl) on an identical dose of GlucoNovax in combination with biguanides (Metformin) denoted as group 1. At the same time the dose of biguanides (Metformin) was not altered for the period of the study. 10 patients with T2D switched from receiving other forms of Glimepiride (Amaryl) on an identical dose of GlucoNovax denoted as group 2.10 patients with T2D switched to the drug GlucoNovax from the drug Glibenclamide denoted as group 3. The control group received monotherapy with Amaryl it consist of 10 patients with T2D denoted as group 4. The severity of diabetic complaints in patients receiving the combination drug GlucoNovax with metformin significantly decreased by the end of the observation period and had an inclination to reduction in the 2nd and 3rd groups, along with the control group. 30 patients, receiving the drug Gluco Novax, 7 achieved blood glucose level parameters that corresponding to the high effectiveness of the drug (4 of them from 1st group (GlucoNovax+ Metformin), 1 in the 2nd group, 2 in the 3rd group). 6 patients achieved blood glucose levels parameters, meeting the criteria of moderate effectiveness of the drug (4 of them from 1st group, 1 patient in the 2nd and 1 patient in the 3rd groups). The given result may be, associated with initially high levels of compensation of carbohydrate metabolism, as well as a more effective influence on combination treatment with Metformin. The drug GlucoNovax appears to be an effective hypoglycemic agent in the treatment of T2D with good tolerability.

Keywords: Diabetes, Gluco Novax, efficacy, tolerability, clinical trial,

INTRODUCTION

Diabetes is a significant public health problem that distresses 285 million people worldwide (Schwatz *et al*., 2010). The occurrence of diabetes worldwide will be double by 2030 (Wild *et al*., 2004). Complications of diabetes include renal failure, neuropathy and peripheral vascular disease with the potential for loss of limbs, retinopathy with augmented risk of impaired vision, and greater than before risk of cardiovascular disease and stroke, which are concomitant with poorly controlled diabetes (WHO, 2012). Good glycemic control can prevent or delay microvascular complications related to chronic diseases, as shown in the Survey of Diabetes UK (UKPDS) and the landmark Diabetes Control and Complications Trial (UKPDS, 1998; N Engl J Med., 1993). The pathophysiology of (T2D) is described by the comparative reduction in insulin secretion and / or insulin resistance. Insulin resistance is a complex phenomenon exacerbated by obesity, especially central obesity, and is believed to start at an early age due to hyperinsulinemia is observed in preadolescents when both parents have diabetes (Fujimoto, *et al*., 1994). T2D results in progressive loss of insulin secretion and UKPDS showed that loss of ≥50% of beta cells had occurred by the time of diagnosis. Thus, beta cells secretagogues are useful to achieve sufficient glycemic control (Robertson *et al*., 1973; Reaven *et al*., 1988). Glimepiride is the latest generation sulfonylureas for the treatment of T2D (Hamaguchi *et al*., 2004). It has a lower cardiovascular risk than conventional sulfonylureas make (Rendell 2004; Nissen *et al*., 2008; Schotborgh *et al*., 1997). Recent tests randomize Control (ACE) they found that it is comparable to metformin in the treatment of patients with T2D (Yamanouchi *et al*., 2005; Yoon *et al*., 2011), including those that are not responding well to sulfonylureas glimepiride not (Rong *et al*., 2004; Wang *et al*., 2009). Probably due to the late start of glimepiride (HMR's amaryl launched for diabetes 1996) and the lack of comparative RCTs head to head in early UKPDS, ADA and NICE recommendations did not include the results of RCTs that matched metformin with glimepiride

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monotherapy they did, but include the results sulfonlyureas had greater than before risk of Obesity, Cardiovascular problems and hypoglycemia. Recent cohort studies confirm the increased cardiovascular risk of glimepiride (Schramm *et al*., 2011) but made no cardiovascular damage for patients with diagnosed (Pantalone *et al*., 2012) coronary artery disease. This study intended to associate the efficacy between metformin and glimepiride monotherapy for T2D through a meta-analysis and provide the evidence that was missing from earlier reviews (Bennett *et al*., 2011; Marre *et al*., 2002) and clinical guidelines (The National Collaborating Centre, 2008; Associate American Diabetes, 2013). The aim of this study is to examine the efficacy and tolerability of the product GlucoNovax-tablets 2 mg № 20 (2x10) (blisters) contains Glimepiride as an active ingredients whereas excipients are Lactose monohydrate, magnesium stearate, cellulose microcrystals, Poloxamer 188, Povidone and Sodium starch glycolate. This medicine is produced for Herbion Pakistan (Pvt.) Limited Karachi (Pakistan). To evaluate the effects of the study drug on the state of glucose metabolism in patients with T2D. To evaluate the tolerability and possible side effects of the study drug, to assess the frequency and severity of hypoglycemia. To evaluate the effects of the study drug on quality of life of patients.

MATERIALS AND METHODS

Type of study

The given clinical trial was carried out as a limited program, as an open-label study.

G*eneral description of the study*

The present study was carried out in accordance with the requirements of annexes, № 1 and 2 by the Order of Ministry of Health Republic of Uzbekistan №.334 dt. 25.07.2001 by the Republic of Uzbekistan for limited clinical trials. This study is approved by ethical committee of Republic of Uzbekistan. The study included 40 patients with T2D who were receiving outpatient treatment at RSNPMTS Endocrinology center Ministry of Health Russia, and corresponding to criteria for inclusion/ exclusion. 10 patients with T2D switched from receiving other forms of Glimepiride (Amaryl) on an identical dose of GlucoNovax in combination with biguanides (Metformin) denoted as group 1. At the same time the dose of biguanides (Metformin) was not altered for the period of the study. 10 patients with T2D switched from receiving other forms of Glimepiride (Amaryl) on an identical dose of GlucoNovax denoted as group 2. 10 patients with T2D switched to the drug GlucoNovax from the drug Glibenclamide denoted as group 3. The control group received monotherapy with Amaryl it consist of 10 patients with T2D denoted as group 4. Every study subject in the given trial was assigned an inclusion serial number, which was entered in the individual registration form. Potential participants of the study were explained the conditions of the trial, they were acquainted with the "List of information for patient" and gave written permission to participate in the study. Patients received treatment for duration of 3 months. In the course of study each patient underwent clinical and laboratory examination in accordance with the scheme set out. All study data of patients were entered in individual patient registration form and ambulatory card. In the case of early discontinuation of a patient from the study, the investigator did not make the replacement. The new patient was assigned the following serial number. The reasons for early dropout from the study were specified in the individual registration form.

Schedule of study and selection of subjects

The study was carried out in a period of 6 months and 40 patients included in this study.

Inclusion criteria of patients in the study

Men and women; age 30 - 70 years; diagnosis: diabetes type 2; informed written consent of the patient to participate in the study. The patient's ability to adequately collaborate in the investigation process.

Exclusion criteria

Patients age younger than 30 and older than 70 years; diabetes type 1; pregnancy, lactation; known hypersensitivity to the sulfonylurea derivative drugs and other drug ingredients; presence of diabetes complications (ketoacidosis, hyperosmolar, coma, precoma, purulent-necrotic complications of diabetes, proliferative retinopathy, nephropathy IV degree, CRF Chronic Renal Failure); presence of concomitant decompensated diseases or acute conditions capable of significantly affecting the result of the study (including chronic hepatitis, liver failure, concomitant infections, sepsis, myocardial infarction, stroke); the need to prescribe concomitant methods of treatment that may affect the results of the study (synergy, antagonism, drug interactions); participation in any other clinical trial for a period of 2 months, prior to inclusion in this study; absence of informed consent of the patient to participate in the clinical trial.

Conditions of elimination of patients from the study

Individual intolerance to the study drug; occurrence of heavy and / or unexpected adverse events in a patient during the study; significant deterioration of the general condition during the study period; non-compliance of the prescribed drug regime; refusal of patient to participate in the study. Each case of patient elimination from the study was recorded in the report indicating its reasons.

Treatment plan

The drug GlucoNovax was prescribed per oral before or during breakfast. The starting and maintenance doses

were determined individually based on the results of glucose control levels in blood and urine. The course of treatment, within the framework of this study for each patient consisted of 3 months.

Concomitant treatment

While conducting the study, all patients were assigned to the appropriate diet and encouraged follow regular exercise regime. During the study period in all groups of patients drugs were prescribed, according to indications used to treat complications of diabetes mellitus (angioprotectors, hepatoprotectors, vitamins and others), as well as remedies, regularly used for treatment of concomitant diseases in doses, not changed during the period of conducting the clinical trials. All drugs, used for concomitant medications, were recorded, including name, dose, route of administration, frequency of administration, starting and ending dates of therapy in the medical history and individual registration form. During the process of investigation the following medicinal remedies were not assigned: other hypoglycemia-causing agents; glucose or drugs based on sugar syrup (except in cases of hypoglycemia); hormonal contraceptives, glucocorticosteroids, anabolic steroids; NSAIDs; MAO inhibitors; tricyclic antidepressants; diuretics; sympathomimetics; on-selective beta-blockers; sulfanilamides; Thyroid hormones.

Conducting tests and methods used: Set of patients

The set of subjects was carried out among patients, referred to the doctor with complaints, appropriate for the inclusion in this study.

RESULTS

Criteria for evaluating effectiveness

The degree of normalization of laboratory parameters, characterizing carbohydrate metabolism; The degree of reduction in severity of typical diabetic complaints from patient's side, as well as the frequency and severity of hypoglycemia.

Evaluation of effectiveness of the investigation drug

For analyzing effectiveness, only those patients were included who had received the full course of treatment of the study drug. The evaluation of effectiveness of the study drug was done based on the below mentioned criteria in points using the following scale:

The following data were obtained as a result of the conducted study: in the group, receiving drug combination of GlucoNovax with Metformin for 3 months of the study showed a significant reduction in fasting plasma glucose (mean of 3.11 mmol/l, $p<0.05$ compared to baseline), in postprandial blood glucose (mean of 5.29 mmol/l, $p<0.05$) and HbA1c (at 0.83%, $p<0.05$). In the group of patients, switched from the drug Amaryl to the drug Gluco Novax, fasting blood glucose insignificantly decreased by 2.85 mmol/l and significant reductions were noted of such indicators, as postprandial blood glucose (of 3.15 mmol/l, $p<0.05$) and HbA1c (of 1.21%, $p<0.05$) after 3 months of study drug administration. In the group of individuals, switched to the drug GlucoNovax from the drug Glibenclamide, there was a tendency to decrease fasting blood glucose levels after meals (by 0.93 mmol/l, $p>0.05$) and HbA1c (by 0.21%) and a significant reduction in plasma glucose (of 3.65 mmol/l, $p<0.05$). In the control group, receiving the drug Amaryl, for 3 months of therapy a significant reduction was obtained in fasting plasma glucose (mean of 2.54 mmol/l, $p<0.05$) and after 2 hours after meals (mean of 4.14 mmol/l, $p<0.05$) and HbA1c of 0.85%, ($p<0.05$). The severity of diabetic complaints in patients receiving the combination drug GlucoNovax with metformin significantly decreased by the end of the observation duration and had a inclination to decline in the 2nd and 3rd groups, along with the control group. Of the 30 patients, receiving the drug Gluco Novax, 7 achieved blood glucose level parameters, corresponding to the high effectiveness of the drug (4 of them from 1st group (GlucoNovax+ Metformin), 1 - in the 2nd group, 2 - in the 3rd group). 6 patients achieved blood glucose levels parameters, meeting the criteria of moderate effectiveness of the drug (4 of them from 1st group, and 1 patient from 2nd and 1 patient from 3rd group. The given result may be, associated with initially high levels of compensation of carbohydrate metabolism, as well as a more effective influence on glycemic control with metformin combination. Dose of the drug GlucoNovax was increased in 2 and decreased in 1 patient of the 1st group, increased by 1 mg in 3 patients of the 2nd group, and in the 3rd group in 2 patients increased, in 2 patients - decreased, which in group analysis was not significant in all 3 groups. Change of drug dose was carried out during re-examination (after 1 month) according to the blood glucose levels parameters. Dose reduction was associated with mild hypoglycemia.

Evaluation of impact of the study drug on the patient's quality of life

Effectiveness of treatment with the study drug in comparison with earlier ongoing treatment (determined by the total severity of subjective complaints): 1-significantly more effective; 2-more effective; 3-no difference; 4-less effective; 5-significantly less effective; Average indicator in the 1st group was 2.8, in the 2nd and 3rd groups-2.88 and 2.8, which corresponds to the criterion of "no difference".

The risk of development of hypoglycemia in comparison with earlier ongoing treatment (considering the frequency and severity of hypoglycemia in the day and night time); 1-reduced; 2-no difference; 3-increased; The given indicator was 1.9 in the first group, 2.0 in the second and third groups.

Table 1: Scheme of patient examination registration of survey data was performed by the following scheme

Days	0*	During the process of investigation after 1 month	During the process of investigation after 2 month	During the process of investigation after 3 month
Visits (observation points)	1	2	3	4
Preliminary assessment of the patient's compliance with inclusion / exclusion criteria	×			
Obtaining the written informed consent of the patient to participate in the study	×			
Objective examination: ▪ registration of patient complaints; ▪ measurement of body weight, heart rate, blood pressure	 × ×	 × ×	 × ×	 × ×
Laboratory tests: ▪ CBC ▪ urinalysis ▪ fasting blood glucose ▪ blood glucose 2 hours after eating ▪ determination of daily diuresis, glycosuria ▪ glycated hemoglobin ▪ ALT	× × × × × × ×	 × × × 	 × × × 	× × × × × × ×
Identification and registration of the possible side effects		×	×	×
Assessment of impact of the study drug on the patient's quality of life		×	×	×
Assessment of tolerability		×	×	×
Assessment of effectiveness				×

0* - Prescription of treatment with drug GlucoNovax;
Note: Measurement of blood glucose level was carried out in laboratory conditions. All survey data of patients were included in the patient's ambulatory card and individual registration form.
While questioning the patient, typical diabetic complaints were taken into account: dry mouth frequent and copious urination itching of the skin and mucous membranes weakness, fatigue
Evaluation of symptoms' severity was performed in points using the following scale: 0 - absence; 1 - insignificant severity; 2 - moderate severity; 3 - significant severity.
Also, the frequency, periodicity and nature of hypoglycemic reactions were taken into account.

Table 2: The degree and severity of hypoglycemia

Light	hypoglycemia occurs independently or after administration of easily digestible carbohydrates by mouth
heavy	for relieving hypoglycemia, requires intravenous administration of glucagon or glucose.

Table 3: Evaluation of effectiveness

3 points	*high effectiveness*	• fasting blood glucose in the range of 4.0 - 6.5 mmol/l • postprandial blood glucose no higher than 8.0 mmol/l • absence of typical diabetic complaints • HbA1c less than 7.0%
2 points	*moderate effectiveness*	• fasting blood glucose in the range of 6.5 – 7.5 mmol/l • postprandial blood glucose no higher than 10.0 mmol/l • severity of typical diabetic complaints not higher than 1 point • HbA1c less than 7.5%
1 point	*low effectiveness*	Presence of at least one of the following criteria: • fasting blood glucose higher than 7.5 mmol/l • postprandial blood glucose higher than 10.0 mmol/l • severity of typical diabetic complaints 2-3 points • HbA1c higher than 7.5%

Convenience of administration of given dosage form of the drug (considering the conditions of storage, transportation, dosing and drug administration); A - drug is convenient; B - drug is inconvenient (specify reason). The drug was convenient during questioning of all patients. Not a single patient specified that the drug was inconvenient.

Table 4: Evaluation of tolerability

5 points	very good (no side effects were recorded)
4 points	Good (insignificant side effects were observed, not inflicting serious problems to the patient and not requiring withdrawal of the drug)
3 points	Satisfactory (side effects were recorded, causing impact on the patient's condition, but not requiring withdrawal of the drug)
2 points	Unsatisfactory (undesirable side effect occurs, causing significant negative impact on the patient's condition and requiring withdrawal of the drug)
1 point	highly unsatisfactory (a side effect, requiring withdrawal of the drug and application of additional medical measures)

Limitations, associated with intake of food and physical activity; A – decrease; B - no difference; C – increase; there was no difference in all groups

Necessity for additional control of glycemic level; A – decreases; B - no difference; C – increases; there was no difference in all groups

Evaluation of tolerability of the study drug

Drug tolerance was evaluated on the basis of subjective symptoms and feelings reported by the patient and the objective data obtained by the investigator during the treatment process. Taken into consideration were the dynamics of laboratory indicators, as well as the frequency of occurrence and nature of adverse reactions. Drug tolerance was evaluated by the investigator (according to subjective data) and by the patient (according to subjective feelings) in points:

Side effects during the drug treatment with GlucoNovax can be: Hypoglycemia with signs such as pallor, increased perspiration, palpitations, sleep disturbances, tremor; neurological disorders (rare), hypoglycemic precoma and coma; Diarrhea, nausea vomiting and abdominal pain. The deterioration of liver function (cholestasis, jaundice), hepatitis, hepatic failure; Allergic reactions (urticaria, erythema, morbilliform or maculopapular rash, late skin porphyria, photosensitivity, allergic vasculitis); Hematological reactions (leukopenia, thrombocytopenia, , pancytopenia, agranulocytosis, hemolytic anemia, aplastic anemia) Hyponatremia, syndrome of defective antidiuretic hormone; Variations in accommodation and / or blurred vision due to hyperglycemia. In the second group in one female patient, on the 5th day of drug administration there occurred an exacerbation of gastric ulcer, in connection with which the patient was eliminated from the study. On average, the evaluation of tolerability in the 1st group was 4.82, in the second - 4.44, in the third - 4.8 points (good and very good).

Termination of the study (withdrawal of the drug)

In the 1st group of patients withdrawal of the drug did not happen. In the second group one female patient dropped from the study on the 5th day in connection with exacerbation of gastric ulcer, 1 patient did not appear for re-examination. In the 3rd group, in 1 patient the drug was withdrawn in connection with hyperglycemia, 1 patient did not appear for re-examination.

DISCUSSION

The outcome demonstrated that when the therapeutic treatment goals for diabetes are not reached, early progression to combination therapy can maintain adequate control of blood glucose in comparison to single agent therapy (U.K. Prospective Diabetes Study Group, 1998). There are very few head-to-head studies that compare the effect between different combinations of anti-diabetic agents. In the present study, we discuss the four groups, patients is taking metformin+Gluco Novax, patient is convert from amaryl to Gluco Novax, patients of is converted from Glibenclamide to GlucoNovax and patient of is taking amaryl. GlucoNovax (glimepiride) is a third-generation sulfonylurea that exhibit several extrapancreatic effects on muscle and adipose cells, elevating active glucose transport and increasing insulin secretion (Mûller, Satoh, & Geisen, 1995). The investigation has methodological strength, obtained through controlling several variables by means of strict selection criteria, as a result of which both groups have similar clinical and laboratory basal characteristics, which did not have significant changes throughout the study. The medical nutritional therapy was permanently evaluated and modified in accordance to the individual characteristics of the patients; however, they did not receive specific indications to increase their physical activity, and this is another limitation of the study, independently of the probability of equilibrium of such characteristic in all 4 groups due to the randomized design. The first clinical experience with the glimepiride/ metformin combination was published in a study wherein metformin failed as monotherapy; in the same study, a diminution of HbA1c of 0.7% was reached after 4 months of treatment (Charpentier, Fleury, Kabir, Vaur, & Halimi, 2001). On the other hand, one more study published the use of glimepiride/metformin in a single dose during a 3-month follow-up study, demonstrating its efficacy and safety in patients with type 2 diabetes with secondary

Table 5: Changes in some indicators in patients before and after treatment with Gluco Novax 2mg

Indicators	GlucoNovax + Metformin, n=10		P	Amaryl → GlucoNovax, n=8		P	Glibenclamide → GlucoNovax		P	Control (Amaryl)		P
	Baseline	After 3 months		Baseline	After 3 months		Baseline	After 3 months		Baseline	After 3 months	
Glycated hemoglobin,%	8.12 ± 0.44	7.29 ± 0.45	<0.05	8.65 ± 0.82	7.44 ± 0.73	<0.05	8.33 ± 0.31	8.12 ± 0.53	n.s.	8.70 ± 0.43	7.85 ± 0.34	<0.05
Fasting blood glucose, mmol/l	9.10 ± 1.27	5.99 ± 0.84	<0.05	9.09 ± 1.61	6.24 ± 0.78	n.s.	8.12 ± 0.94	7.19 ± 1.05	<0.05	8.74 ± 0.73	6.20 ± 0.32	<0.05
Postprandial glycemia, mmol/l	13.83 ± 1.24	8.54 ± 1.12	<0.05	12.89 ± 1.63	9.74 ± 1.03	<0.05	13.52 ± 1.29	9.87 ± 1.05	n.s.	13.66 ± 0.77	9.52 ± 0.91	<0.05
Sugar in urine, %	0.53 ± 0.22	0.06 ± 0.07	n.s.	0.45 ± 0.33	0.19 ± 0.20	n.s.	0.63 ± 0.28	0.44 ± 0.26	n.s.	0.62 ± 0.25	0.10 ± 0.09	n.s.
Diabetic complaints, points	1.8	0.8	<0.05	1.9	1.3	n.s.	1.7	1.2	n.s.	1.9	0.7	n.s.
Dose of glimepiride, mg	1.73 ± 0.15	1.82 ± 0.19	n.s.	1.88 ± 0.13	2.25 ± 0.17	n.s.	1.75 ± 0.14	1.88 ± 0.24	n.s.	1.90 ± 0.12	1.91 ± 0.13	n.s.
Dose of metformin, mg	1079.55 ± 166.76	1063.64 ± 160.17	n.s.	-			-					
ALT, mcmol/l	0.47 ± 0.03	0.46 ± 0.02	n.s.	0.43 ± 0.02	0.46 ± 0.02	n.s.	0.48 ± 0.02	0.50 ± 0.02	n.s.	0.45 ± 0.05	0.43 ± 0.04	n.s.
Evaluation of effectiveness, points	2.09			1.38			1.50					
Evaluation of tolerability	4.80			4.44			4.80					

failure to glibenclamide. In the above mentioned study, reduction of HbA1c was of 1.3% and approximately half of the patients showed an HbA1c reduction of at least 1%. Nevertheless, only a small percentage of patients reached the A1C goal of less than 7% (González-Ortiz *et al*., 2004). In accordance with the new ADA-EASD guidelines, a sulfonylurea combined with metformin constitutes an attractive option in the clinical practice (American Diabetes Association, 2008). This combination can reduce A1C concentration up to 2% (Krentz & Bailey, 2005). In our study group 1, receiving drug combination of GlucoNovax with Metformin for 3 months of the study showed a significant reduction in fasting plasma glucose (mean of 3.11mmol/l, $p<0.05$ compared to baseline), in postprandial blood glucose (mean of 5.29mmol/l, $p<0.05$) and HbA1c (at 0.83%, $p<0.05$). In the group 2 of patients, switched from the drug Amaryl to the drug Gluco Novax, fasting blood glucose insignificantly decreased by 2.85 mmol/l and significant reductions were noted of such indicators, as postprandial blood glucose (of 3.15mmol/l, $p<0.05$) and HbA1c (of 1.21%, $p<0.05$) after 3 months of study drug administration. In the group 3 of individuals, switched to the drug GlucoNovax from the drug Glibenclamide, there was a tendency to decrease fasting blood glucose levels after meals (by 0.93mmol/l, $p>0.05$) and HbA1c (by 0.21%) and a significant reduction in plasma glucose (of 3.65mmol/l, $p<0.05$). In the group 4, receiving the drug Amaryl, for 3 months of therapy a significant reduction was obtained in fasting plasma glucose (mean of 2.54mmol/l, $p<0.05$) and after 2 hours after meals (mean of 4.14mmol/l, $p<0.05$) and HbA1c of 0.85%, ($p<0.05$). The severity of diabetic complaints in patients receiving the combination drug GlucoNovax with metformin significantly decreased by the end of the observation duration and had an inclination to decline in the 2nd and 3rd groups, along with the control group.

CONCLUSION

As a result of the conducted clinical trial on the drug GlucoNovax and on the basis of the data obtained the following conclusion can be made. The drug GlucoNovax seems to be a potent hypoglycemic agent in the management of T2D with good tolerability.

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