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CONFIRM

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CLINICAL STUDY REPORT

**DIETARY SUPPLEMENT
INULIN - NUTRIMED**

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INTRODUCTION

It was known long ago about a good clinical effect while using chicory and ground pear roots in treatment of diabetic patients in folk as well as in scientific medicine / 1 /. One of the main acting substances in both plants is inulin, which aroused interest to above mentioned substance. In 1999 Pavliuk P.M. proved the existence of reliable sugar-reducing hypocholesterolemic effect of the preparation INULIN – NUTRIMED for the diabetes of the type 2 / 2 /. Doctor Kosyh O.Y. proved the reduction of the sugar and cholesterol level in blood as the result of administration of INULIN – NUTRIMED / 3 /.

It is known that the most stable and informative indicator of diabetes compensation is the level of glucose hemoglobin of blood. Though we have not found the influence of inulin on this indicator in available literature, and this direction of research work seems to be very important for providing positive influence of the medicine on hydrocarbon metabolism among diabetic patients.

STUFF AND METHODS

Diet supplement of plant origin INULIN – NUTRIMED made by the joint – stock company Nutrimed, Ltd, was the object of research work. It is a 100% diet supplement including polysaccharide made from chicory roots and encapsulated in 500 Mg capsules. INULIN – NUTRIMED is admitted to production and usage in food / a medical – prophylactic product / in accordance with HYGIENIC CONCLUSION of the STATE SANITARY – HYGIENIC EXAMINATION of HOME PRODUCTION under No 5.08.07/2056 dated June 14, 1999.

31 diabetic patients with diabetes of the second type, including 18 men and 13 women aged 37 – 74 years were examined. All the patients were divided into two groups: the first group included the patients with the first discovered diabetes, and the second group – with long-term diabetes of the 2 type.

The first group consisted of 9 patients, including 3 women and 6 men with the first discovered diabetes 2 in the stage of decompensation. Patients were prescribed the medicine INULIN – NUTRIMED 2 capsules 3 times a day, they did not take other sugar-reducing medicines.

The second group consisted of 22 diabetic patients of the second type in the age from 6 months to 21 years, including 12 men and 10 women. These patients regularly took the sugar-reducing medicines – mainly glybenclamide, but diabetes also was in the stage of decompensation. Dose of the sugar-reducing medicines was the same for the patients of this group the whole examination period.

But they were also prescribed INULIN –NUTRIMED 2 capsules 3 days a day during the two – months period in addition. The patients of both groups were on the standard diet No 9.

A period of taking the medicine INULIN – NUTRIMED was equal to two months period. All the patients were tested for the concentration of cholesterol, B- lipoproteins, glycolized hemoglobin and hemoglobin in blood on an empty stomach, glucose in blood in two hours after having meals and amount of glucose in daily urine. A clinical examination of the patients has also been held. Determination of glycolized hemoglobin was carried out using colorimetric methods applying thiobarbiturate acid, as to other indicators – means of standard laboratory method have been used.

Laboratory data was processed by means of variation statistics method with calculating averages and their standard approximate values taking Student's criterion into account. To estimate reliability of obtained results $P < 0,05$ has been taken as the notional level.

TABLE 1

Influence of the diet supplement INULIN – NUTRIMED on the glucose level in blood of patients with diabetes of the type II (in mMolars/ l)

Groups of patients	Before treatment	In a month	In 2 months	P ₁₋₂	P ₁₋₃	P ₂₋₃
All patients	9,6 ± 0,4	8,1 ± 0,4	7,0 ± 0,3	<0,05	<0,001	<0,05
Patients with type 2 diabetes discovered for the first time	9,3 ± 0,7	7,5 ± 0,9	6,1 ± 0,5	>0,05	<0,01	>0,05
Patients with the long- term type 2 diabetes	9,7 ± 0,5	8,3 ± 0,5	7,3 ± 0,3	>0,05	<0,001	>0,05

TABLE 2

Influence of the diet supplement INULIN – NUTRIMED on the postprandial glucose level in blood of patients with diabetes of the type 2 (in mMolars/ l)

Groups of patients	Before treatment	In a month	In 2 months	P ₁₋₂	P ₁₋₃	P ₂₋₃
All patients	11,5 ± 0,6	9,5 ± 0,5	8,8 ± 0,3	<0,05	<0,001	>0,05
Patients with type 2 diabetes discovered for the first time	12,4 ± 1,4	10,0 ± 1,3	8,5 ± 0,5	>0,05	<0,05	>0,05
Patients with the long- term type 2 diabetes	11,2 ± 0,5	9,2 ± 0,5	8,9 ± 0,4	<0,01	<0,001	<0,001

TABLE 3

Influence of the diet supplement INULIN – NUTRIMED on daily glucosuria level in blood of patients with diabetes of the type 2 (in g)

Groups of patients	Before treatment	In a month	In 2 months	P ₁₋₂	P ₁₋₃	P ₂₋₃
All patients	41 ± 9	17 ± 5	8 ± 2	<0,05	<0,001	>0,05
Patients with type 2 diabetes discovered for the first time	55 ± 23	15 ± 8	3 ± 2	>0,05	>0,05	>0,05
Patients with the long- term type 2 diabetes	35 ± 9	17 ± 6	10 ± 3	>0,05	<0,001	>0,05

P₁₋₂ – level of notional differences between indicators before and in a month after beginning the treatment according the Student's criterion;

P₁₋₃ – according to indicators before and in 2 months after beginning the treatment;

P₂₋₃ – according to indicators in a month and in 2 months after beginning the treatment .

TABLE 4

**Influence of the diet supplement INULIN – NUTRIMED
on the glycolized hemoglobin level
in blood of patients with diabetes of the type 2 (in %)**

Groups of patients	Before treatment	In a month	In 2 months	P ₁₋₂	P ₁₋₃	P ₂₋₃
All patients	6,93 ± 0,35	6,50 ± 0,25	5,92 ± 0,17	>0,05	<0,05	>0,05
Patients with type 2 diabetes discovered for the first time	7,53 ± 0,60	7,32 ± 0,62	5,79 ± 0,41	<0,05	<0,05	<0,05
Patients with the long- term type 2 diabetes	6,69 ± 0,42	6,24 ± 0,25	5,97 ± 0,18	>0,05	>0,05	>0,05

TABLE 5

**Influence of the diet supplement INULIN – NUTRIMED
on the cholesterol level
level in blood of patients with diabetes of the type 2 (in mMolars / l)**

Groups of patients	Before treatment	In a month	In 2 months	P ₁₋₂	P ₁₋₃	P ₂₋₃
All patients	5,2 ± 0,2	5,5 ± 0,2	4,5 ± 0,2	>0,05	<0,05	<0,01
Patients with type 2 diabetes discovered for the first time	5,3 ± 0,3	4,8 ± 0,5	4,7 ± 0,4	>0,05	>0,05	>0,05
Patients with the long- term type 2 diabetes	5,2 ± 0,2	5,7 ± 0,3	4,4 ± 0,2	>0,05	<0,01	<0,001

TABLE 6

**Influence of the diet supplement INULIN – NUTRIMED
on the B- Lipoproteids level
in blood of patients with diabetes of the type 2 (in g/l)**

Groups of patients	Before treatment	In a month	In 2 months	P ₁₋₂	P ₁₋₃	P ₂₋₃
All patients	5,1 ± 0,3	5,5 ± 0,4	5,2 ± 0,3	>0,05	>0,05	>0,05
Patients with type 2 diabetes discovered for the first time	4,8 ± 0,3	4,9 ± 0,6	5,5 ± 0,6	>0,05	>0,05	>0,05
Patients with the long- term type 2 diabetes	5,2 ± 0,4	5,8 ± 0,4	5,1 ± 0,3	>0,05	>0,05	>0,05

P_{1-2} – level of notional differences between indicators before and in a month after beginning the treatment according the Student's criterion;

P_{1-3} – according to indicators before and in 2 months after beginning the treatment;

P_{2-3} – according to indicators in a month and in 2 months after beginning the treatment .

RESULTS AND THEIR EVALUATION

As we see from the table 1, the whole sugar level in blood of all patients on empty stomach reduced in a month after beginning their treatment, $P < 0,05$, and its reducing continued also in 2 months, $P < 0,01$. Reliable reducing of sugar on empty stomach was also observed in the group of the patients with for the first time discovered diabetes as well as in the group with long-term diabetes of the type 2.

Level of glucose in blood of the patients with the first discovered and long-term diabetes reduced significantly in two hours after taking meals as the result of taking for two months INULIN – NUTRIMED in the whole group / Table 2 /.

Level of daily glucosuria of all the patients significantly reduced in a month and in two months after beginning of therapy / Table 3 /.

Special interest aroused regarding considerable reducing of glycolized hemoglobin from $6,93 \pm 0,35$ % to $5,92 \pm 0,17$ % , $P < 0,05$, in the whole group after taking the preparation INULIN – NUTRIMED during two months / Table 4 /, that is the proof of stable and continuing hypoglycemic effect of this medicine. Under the influence of NUTRIMED – INULIN cholesterol level in blood of all patients has been significantly reduced during two months' treatment / Table 5 / from $5,2 \pm 0,2$ mMolars / l from $4,5 \pm 0,2$ mMolars / l, $P < 0,05$. At the same time the level of B – lipoproteids has not visibly changed during the treatment / Table 6 /. Changes in the weight of the patients have also not been discovered after two months of taking the medicine.

The medicine INULIN – NUTRIMED has not shown any incidental effects during the whole period of research conducted; treatment was well borne by the patients. No cases of allergic reactions against INULIN – NUTRIMED have been registered during the tests.

CONCLUSIONS

1. Diet supplement INULIN – NUTRIMED significantly reduces glucose level in blood on empty stomach and in two hours after taking meals in diabetic patients of the second type as well as daily glucosuria.
2. Treatment of patients with diabetes of type 2 with "INULIN – NUTRIMED" results in reduction of cholesterol's level in blood.
3. Treatment with INULIN – NUTRIMED results in reduction of glycolized hemoglobin level in blood of patients with type 2 diabetes.
4. INULIN – NUTRIMED does not lead to incidental effect allergic reaction.
5. Diet supplement INULIN – NUTRIMED can be recommended to be used as the sugar – reducing medicine and hypocholesterolemic medicine for treatment of the patients with diabetes of the type 2..
6. INULIN – NUTRIMED can be prescribed in monotherapy as well as in combination with other sugar – reducing medicines according to the severity level of the patients.

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