

REPORT

On the Evaluation of the Therapeutic Efficacy of Renohelp USA
in Patients with Chronic Kidney Disease

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Renohelp USA contains dry extract of *Lespedeza capitata*, dry extract of birch (*Betula platyphylla* Suk.), dry extract of cranberry (*Vaccinium vitis-idaea* L.), vitamin E (D-alpha tocopherol), iron (Ferrous gluconate), and vitamin B6 (Pyridoxine HCl). It can be used in patients with impaired renal function, i.e. chronic kidney disease (CKD). In the course of the development of chronic renal disease there is an increase in oxidative stress and asymmetric dimethyl arginine (ADMA) levels. This results in the depletion of nitrogen oxide, impaired vascular tone, impaired vasodilatation, decreased free radicals release, and plaque disruption with thrombus formation. For the treatment of CKD, it is important to overcome these pathogenetic mechanisms.

The use of α -tocopherol by the proximal tubule cells of the kidney reduces cisplatin-induced reactive oxygen species (oxygen free radicals) and increases cell viability. Studies have shown that regular intake of α -tocopherol contributes to lowering ADMA levels.

Elevated homocysteine and reduced folate concentrations or pyridoxal-5-phosphate (PLP - active metabolite of vitamin B6) are characteristic of CKD development. They can cause excessive production of reactive oxygen species leading to greater oxidative stress and reduced antioxidant enzyme activity. The use of vitamin B6 (Pyridoxine HCl) contributes for the reduction of oxidative stress and the possible risks of cardiovascular events.

Oral intake of iron salts is commonly used to treat iron deficiency anemia in CKD patients. Iron ferrous forms are used for better absorption of iron. Good absorption of ferrous gluconate gives better control of iron deficiency in CKD and implies greater safety in its use.

The amounts of vitamin E (α -tocopherol), vitamin B6 (Pyridoxine HCl) and iron (Ferrous gluconate) added to RENOHELP USA are consistent with the recommended daily intake of vitamins and minerals. This makes them suitable for long-term use.

Patients with CKD are characterized by increase in their number. RENOHELP USA suggests a new treatment option for these patients. This allowed us to conduct a clinical trial. It includes 30 patients (15 men and 15 women) and lasts for 3 (three) months. The aim of the clinical study was to determine the therapeutic effect of treatment with Renohelp USA on the kidney function of CKD patients.

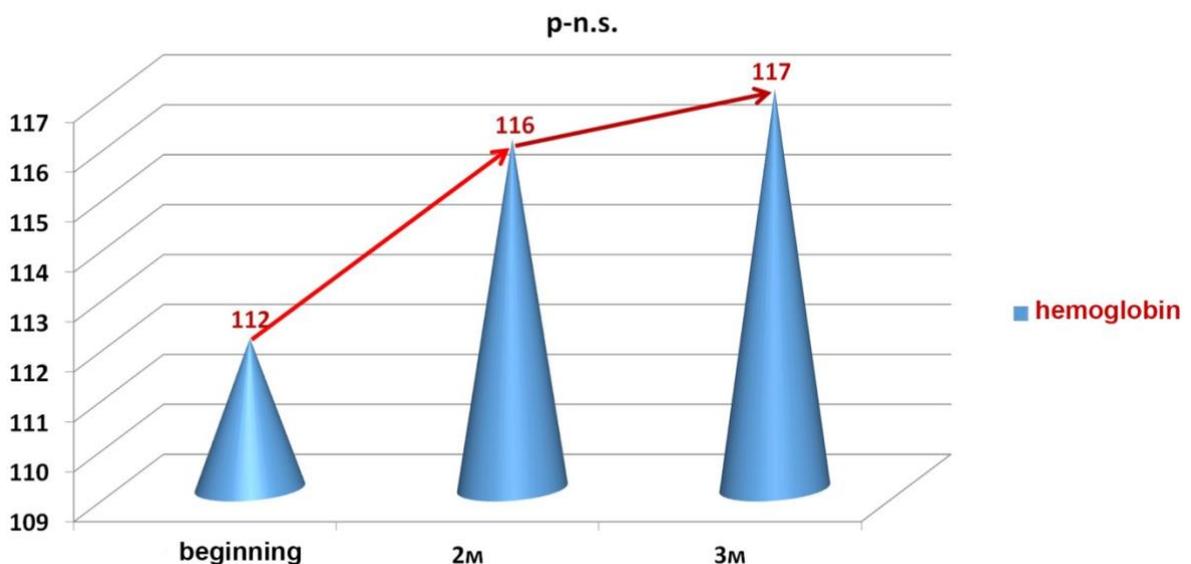
Patients are initially controlled prior to initiation of treatment and have at least two other controls, one of which is at the end, i.e. the end of the 3rd month.

Serum creatinine, glomerular filtration, urea, uric acid, cholesterol, 3-glycerides, GOT, GPT, AF, GTP, bilirubin, blood sugar, K +, Na +, blood count, Fe, Iron binding capacity, blood pressure, microbiological urine test, and side effects of the preparation.

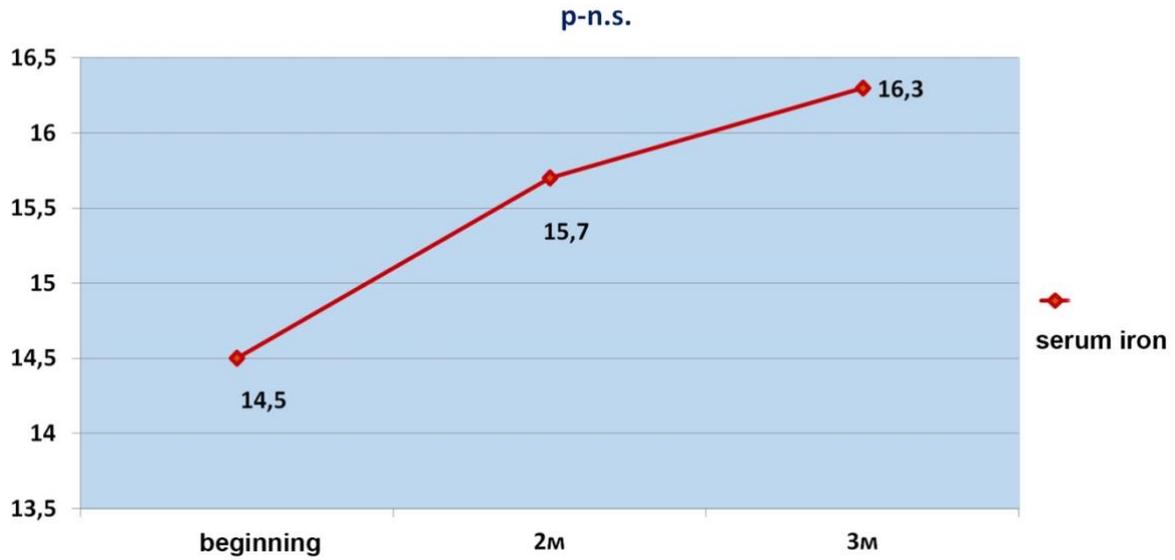
| M : F | Average age (years) | Average GF at the beginning (ml/min) | Mean value of creatinine at baseline (μmol/l) | Average uric acid value at the beginning (μmol/l) | Hemoglobin g/l | Average blood pressure (mmHg) | Average cholesterol values (mmol/l) | Serum iron |
|-------|---------------------|--------------------------------------|---|---|----------------|-------------------------------|-------------------------------------|------------|
| 1:1 | 47±6 | 56±12 | 157±18 | 432±27 | 112±5 | 145(±10) /85(±15) | 6,5±0,7 | 14,5±5 |

RESULTS

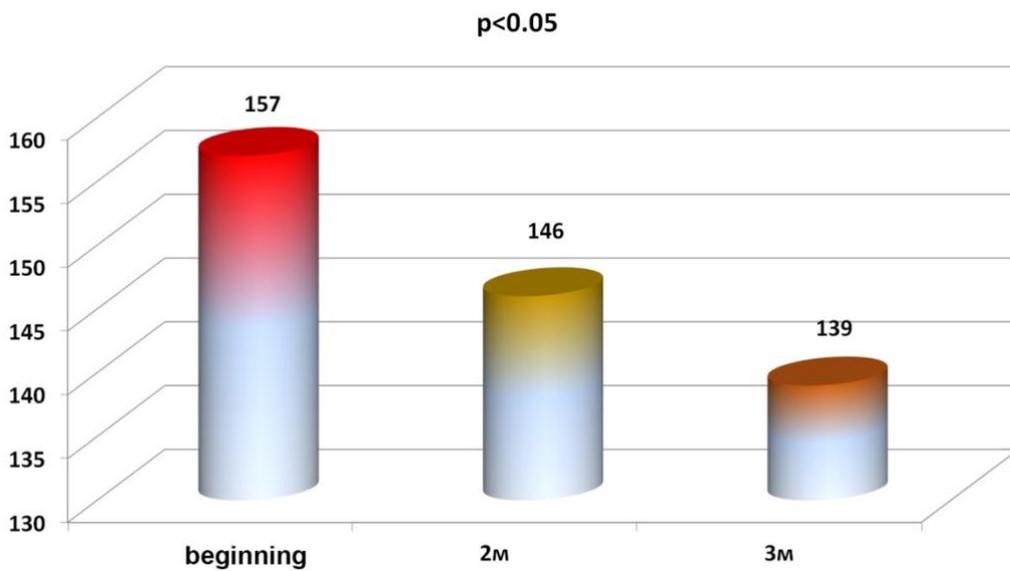
In hemoglobin monitoring, we found a tendency to increase, without statistical justification of the change, presented in the following graph:



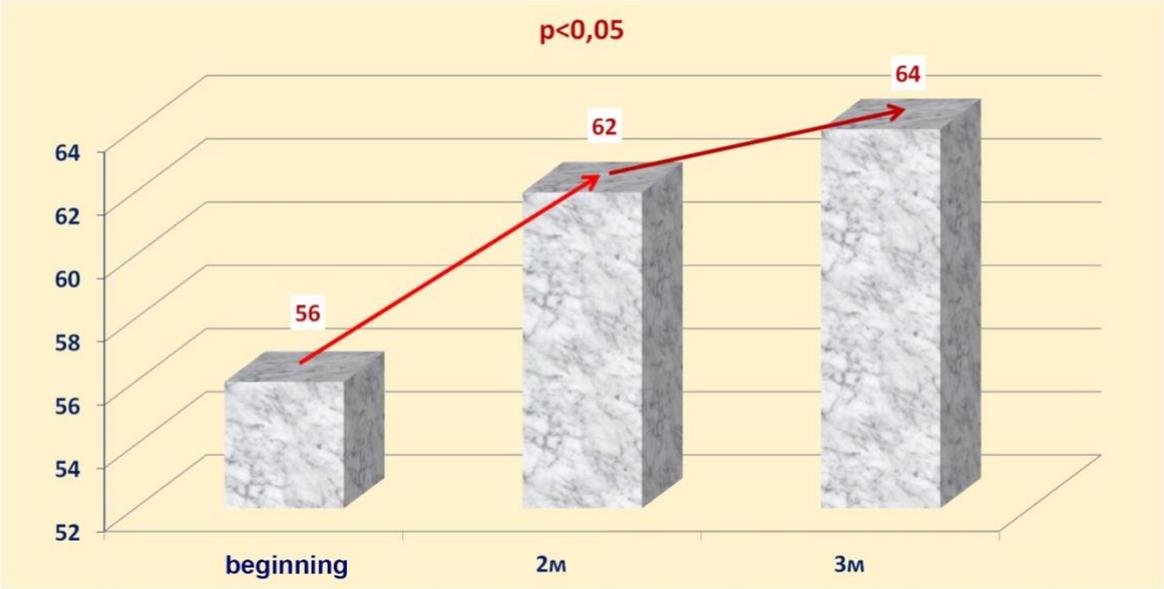
The results showed an increase in serum iron level without statistical justification presented in the following graph:



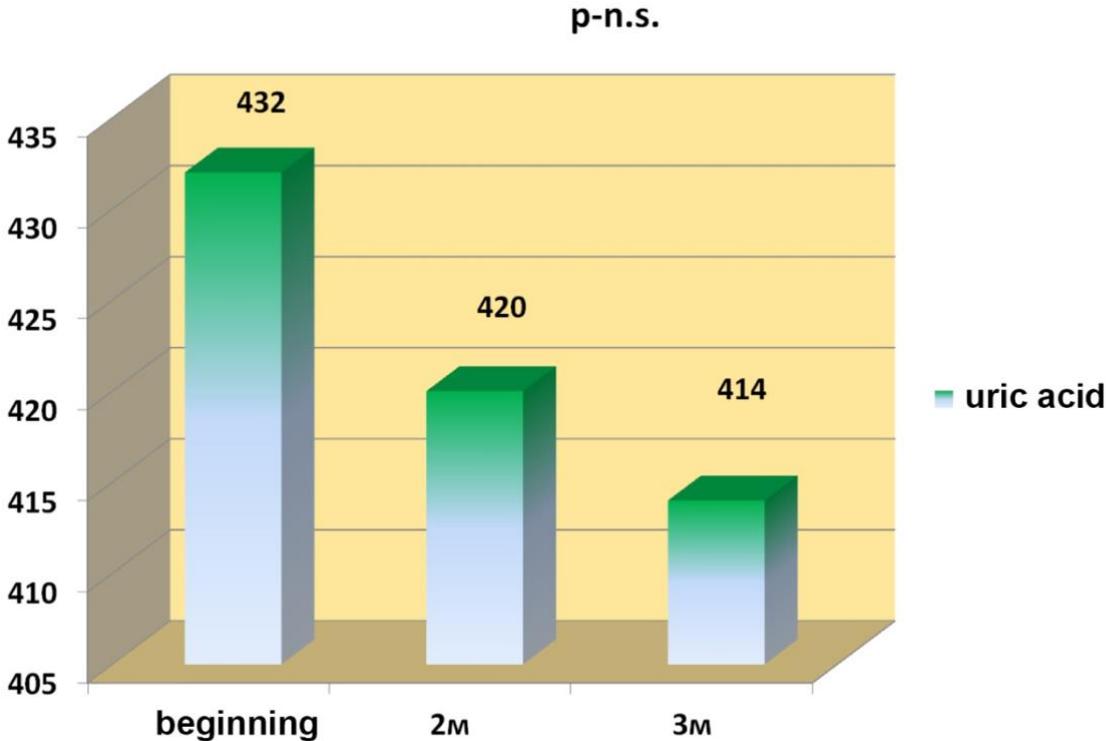
We found a marked change in the serum creatinine level with statistical significance, which clearly demonstrates the effect of improving the renal function of the tested product, presented in the following graph:



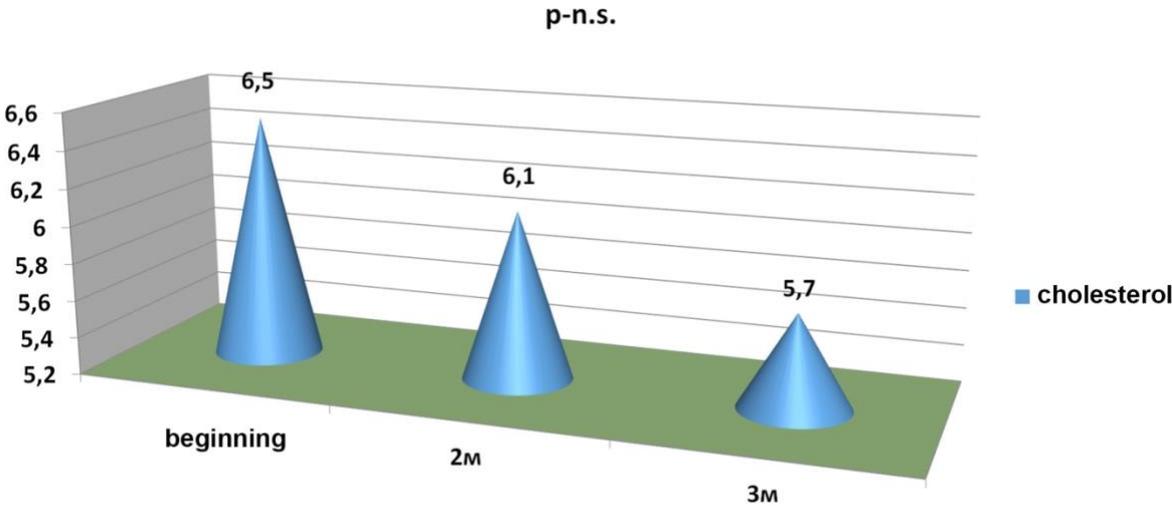
Changes in glomerular filtration in the direction of increase are significantly expressed with statistical significance, which also confirms the positive effect of the product on renal function presented on the following graph:



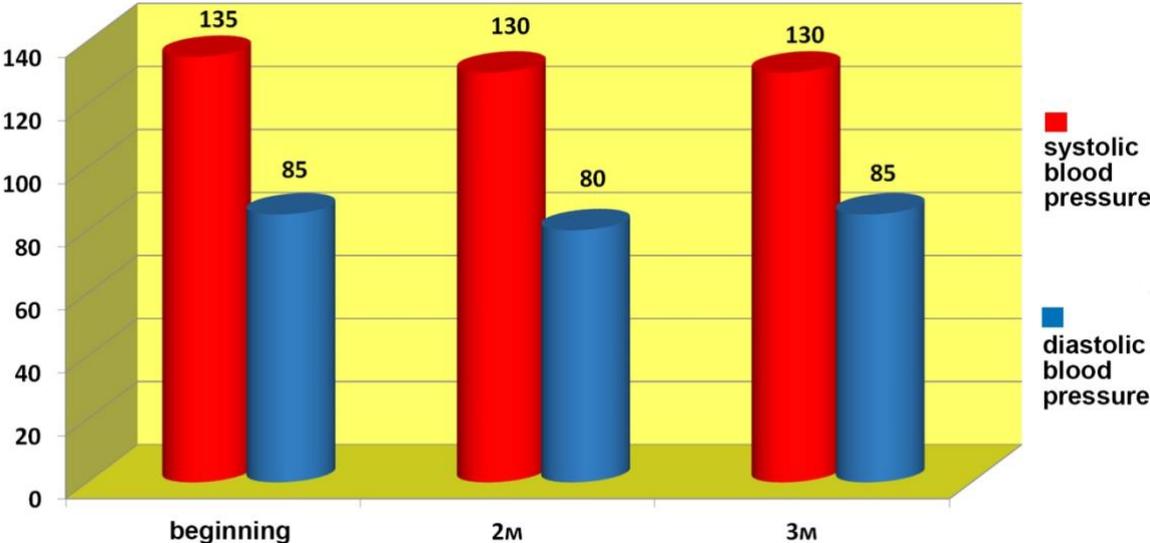
Changes in the uric acid level are in the direction of decrease, but without statistical significance, are presented on the following graph:



Changes in cholesterol level are downward but not statistically significant, as shown in the following chart:



Blood pressure of patients subject to the test continues to be stable within the target values presented on the following graph:



CONCLUSIONS

On the basis of the obtained results we made the following main conclusions:

Administration of Renohelp USA results in a significant decrease in serum creatinine respectively increased glomerular filtration in patients with CKD. This is undoubtedly related to the slowdown of CKD progression.

Administration of Renohelp USA in patients with CKD results in a decrease in uric acid and cholesterol levels, increase in hemoglobin and serum iron, which are not statistically significant but have a tendency to stabilize the condition of patients.

There were no side effects reported by patients participating in the study, and those found by the medical control tests.

The application of Renohelp USA has a positive effect on the slowdown of CKD progression.