



**“Efficacy and safety study of “Fitoguru Supermen Pumpkin-Carrot-Ginger” functional juice drink in men after treatment of acute or chronic prostatitis”**

**in conditions of Altai State Medical University,  
Federal Agency for Healthcare and Social  
Development**



# Altai State Medical University



- ✓ Included in the List of Medical Institutions authorized to conduct clinical trials of medicinal products
- ✓ Today ASMU is one of the leading higher medical education establishments in Western Siberia

**Principal investigator – *B.I. Kozlov* , Doctor of medical sciences, professor, Department of Faculty Therapy**

# Study objectives, type and design

## Purposes and objectives:

- ✓ To study the dynamics of guiding clinical symptoms, parameters of laboratory and functional examinations in almost healthy persons with specific diseases.
- ✓ To evaluate efficacy of Fitoguru drinks in almost healthy persons with signs of specific diseases.
- ✓ To substantiate possibility and safety of drink usage as an adjunct in correction of clinical manifestations of diseases.

## Type:

- ✓ Prospective single-site comparative open-label study.
- ✓ Period: August-December 2010

## Design:

- ✓ Fitoguru drinks were used in almost healthy people with clinical manifestations of certain diseases as an adjunct source of bioactive substances in order to study their influence on clinical laboratory and functional parameters as well as quality of life.
- ✓ Number of patients – 40 persons.

# Extent of examinations

## Clinical examination (30 days)

- Complete blood count (haemoglobin, erythrocytes, leukocytes, erythrocyte sedimentation rate)
- Antioxidant state (in plasma – total antioxidant activity and thiobarbiturate-reactive products, in red blood cells – total antioxidant activity, superoxide dismutase, catalase, glutathione peroxidase )
- Assessment of involuntary nervous system tonus by Kareem index

## Urine analysis

- colour, transparency, specific density, reaction, protein, glucose, epithelia, leukocytes, erythrocytes, cylinders, mucus

## Bicycle exercises (functional tests)

- exercise capacity, chronotropic reserve and isotropic reserve, double product index, threshold power, index of metabolic cost

## Quality of life

- WAM scale (Wellbeing, Activity, Mood)
- MFI 20 questionnaire (simplified modification)
- Chronic prostatitis symptom index (NIH-CPSI)
- International index of Erectile Function (IIEF)

# Inclusion and exclusion criteria

## Inclusion criteria

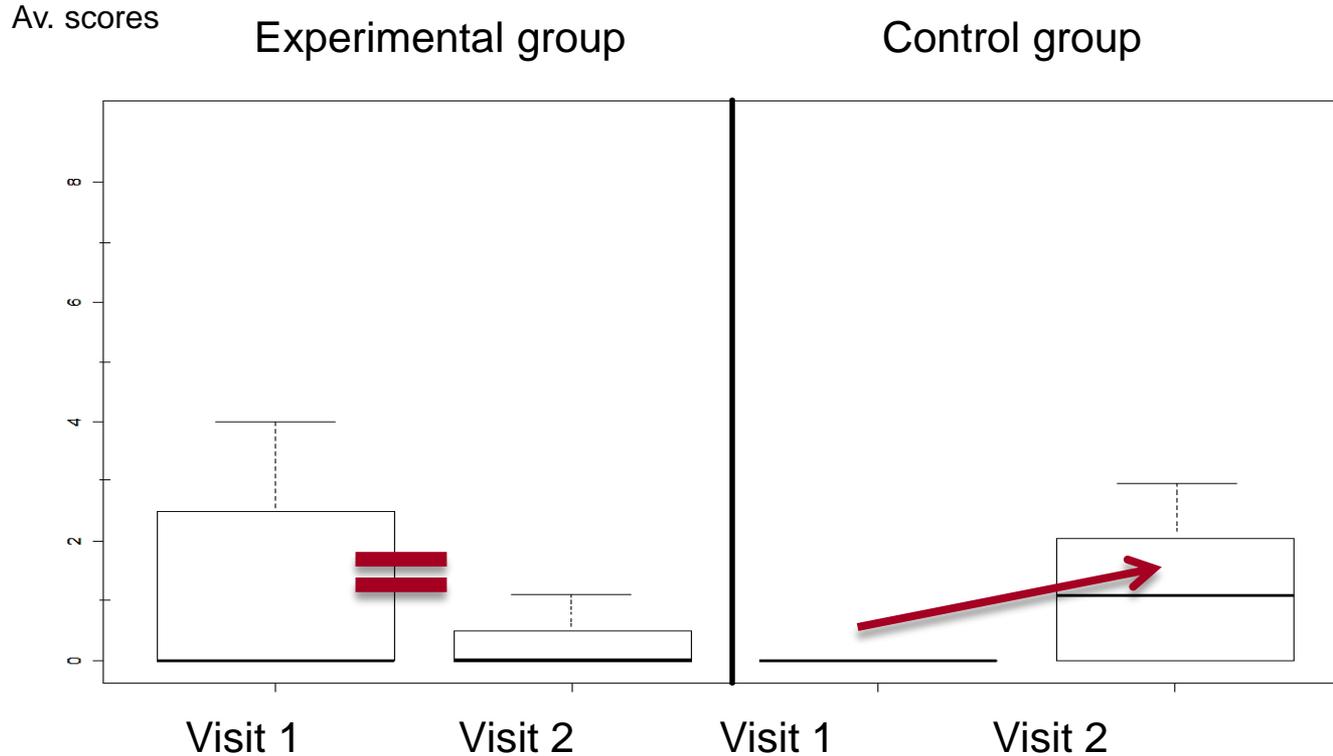
- Patients older than 18 and younger than 64 years of age
- Almost healthy volunteers
- Willingness to comply with protocol procedures
- Written informed consent

## Exclusion criteria

- Idiosyncrasy of product components
- Diabetes
- Phenylketonuria
- Contraindications to bicycle exercises
- Advanced general diseases
- Oncological diseases of any localization, HIV, tuberculosis, alcohol or drug abuse, mental illnesses
- Simultaneous participation in any other clinical study, as well as in the past 30 days
- Pregnancy, lactation

# NIH-CPS scale index(National Institute of Health Prostatitis Symptom Index) – Index of symptoms of chronic prostatitis and pelvic pain syndrome in men according to US National Institute of Health

## Parameter “Pain”



Elongation of effect of the main treatment of prostatitis for  
“Pain”

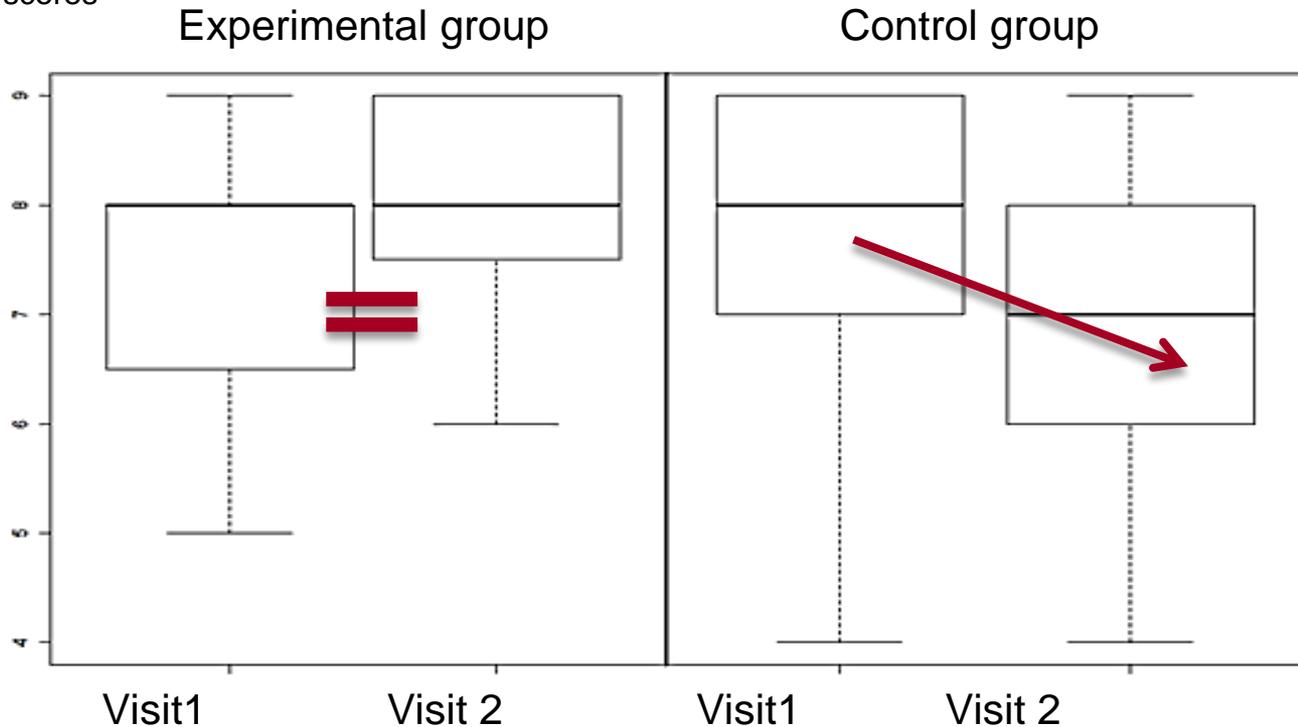
\* - statistically significant differences at the beginning and at the end of the study ( $p < 0.05$ )

# IIEF scale index

(International Index of Erectile Function)

## Parameter “General satisfaction»

Av. scores

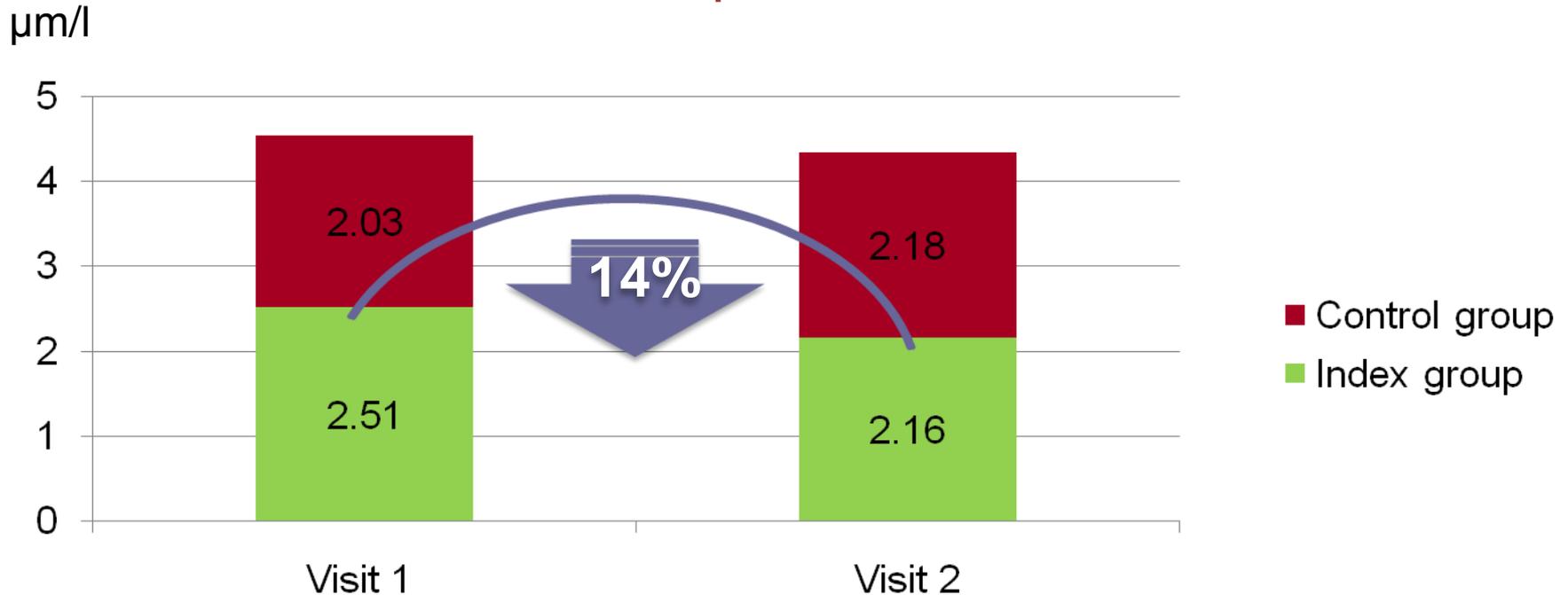


Elongation of effect of the main treatment of prostatitis for “General satisfaction”.

\* - statistically significant differences at the beginning and at the end of the study ( $p < 0.05$ )

# Efficacy

## Dynamics of thiobarbiturate-reactive products content in plasma



Decrease of TBRP in plasma by **14%**.

\* - statistically significant differences at the beginning and at the end of the study ( $p < 0.05$ )

# Conclusion

- ✓ In assessing the severity of symptoms of chronic prostatitis and pelvic pain according to the NIH-CPSI scale a significant reduction for “Pain” was observed in the index group as compared to the control group. In addition, a positive effect of regular drink intake on “General satisfaction” assessed on IIEF scale has been noted.
- ✓ Intake of study product during the period of observation led to positive dynamics of antioxidant protection parameters. Decrease in TB-reactive products in the index group by **14%**.
- ✓ Efficacy and safety study of “FITIGURU Supermen Pumpkin-Carrot-Ginger drink” showed good product tolerability.
- ✓ Safety assessment studies (physical examination, complete blood count, urine analysis) have not showed significant deviations from normal and initial parameters.

**Principal investigator, Chief Researcher,  
Professor, Doctor of Medical Sciences,  
Honored Doctor of the Russian Federation  
Aleksandr Isralievich Neumark :**



*“Based on conducted clinical studies that have shown a possibility of positive influence on certain body functions, it is recommended to consider functional juice drink “FITOGURU Supermen Pumpkin-Carrot-Ginger” containing herbal extracts as a functional purpose-made drink. The drink can be recommended for improvement of functional state of the men genitourinary system as a means to prolong relapse-free period after treatment of prostatitis”.*