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### An attempt to present medication for overlap syndrome dyspepsia with nonspecific/unspecified irritable bowel syndrome by patients' self-assessment

**Introduction:** At present, the Rome V criteria are being developed, with an emphasis on the key aspects for revision of a number of provisions, including elimination of diagnostic problems in the overlap syndrome (Address Diagnostic Overlap). On the other hand, the presence of the “overlap syndrome” worsens the course of and treatment outcomes in such conditions. And the most common symptoms overlap is the combination of Functional Dyspepsia (FD) and Irritable Bowel Syndrome (IBS).

**Methods:** The group for inclusion in the study was selected by questionnaire survey, subject to the basic Rome IV criteria and modified Leeds Dyspepsia Questionnaire validated using more than 18,000 cases. Treatment efficacy assessment was based on Patient-Reported Outcomes (PROs) obtained during the final treatment visit (Visit 3). Effects were detailed according to a special self-assessment questionnaire (medication and treatment satisfactory questionnaires TSQ) validated using 18,724 cases in an earlier study. Additionally, taking into account peculiarities of alverin action, the participants of the study had undergone a grip test.

To assess safety a number of parameters available in routine clinical practice were determined during all visits: blood chemistry values, hematological blood values, urinalysis values. During the randomization visit, hsCRP was determined in all patients; values were below 5 mg/L. Fecal calprotectin was determined by rapid test kit for semi-quantitative, with the cut-off value 50 µg/L to exclude bowel inflammatory and only these patients included in the study. Group A with Meteospasmyl: 21 pts age: 46.5 (95% CI 39.7-53.4), median 45 (Q-25-Q-75=31-60), 23.8% (95% CI (Fisher's) 11.3-52.2%) of males. 5 volunteers were smokers (23.8% (95% CI (Fisher's) 8.2-47.2%). Group B with

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comparator: Height: age- 45.4 (95% CI 35.0-55.9), median 49 (Q-25-Q-75=37-53), 11.1% (95% CI (Fisher's) 0.3-48.2%) of males. Comparison of the analysis results in groups A and B showed that there was no statistically significant difference in height, weight and age. There is a difference in the number of smokers: Group A had a larger number of smokers.

**Results:** The study results showed the high efficiency of the combination alverine with simethicone (Meteospasme) according to self-assessment by patients with overlapping symptoms of UD and IBS-N: positive effect-86.7% (95% CI Fisher's=78.6-92.5) cases and a high Odds ratio (22.7, at 95% CI=8.9-58.4) compared with the control group (treatment without the use of Meteospasme). Treatment adherence higher in 12 times (Odds ratio) (95% CI=1.42-112.06) with Meteospasme (85.7% (95% CI=63.7-97.0), versus the control group (33.3% 95% CI=7.5-70.1). A high safety degree of this drug has been demonstrated, both in terms of clinical and laboratory parameters. Results were obtained confirming the effect of Meteospasme on skeletal muscles with a significant increase in the grip strength of the right hand both at the 2<sup>nd</sup> week of treatment with Meteospasme (increase by 0.4 kg) and by the 4<sup>th</sup> week of treatment (by 0.6 kg), in contrast with comparison group (F test ANOVA (2;60)=7.2; p=0.0015; Kruskal Wallis test-H(2;63)=27.6161; p=0.00001). The applied method of multivariate analysis of variance with a hypothesis decomposition model confirmed the effect of Meteospasme on the increase in the values of hand dynamometry on the 28<sup>th</sup> day of admission (p trend less than 0.001).

## Conclusions:

1. New data were obtained on the option of overlapping UD and IBS-N.
2. Patients' self-assessment of effectiveness in this variant of disorders was not previously studied.
3. Meteospasme demonstrated greater efficiency and high safety profile.
4. Meteospasme increased the functional state of skeletal muscles.

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## Biography

Yury Marakhouski approved as Professor of Clinical Medicine in 2005 year by the Higher Certification Commission of the Council of Ministers of the Republic of Belarus. He is head of the Department Gastroenterology and Nutrition of the Byelorussian Medical Academy of Postgraduate Education. He has published more than 30 papers in reputed journals and serving as a member of the editorial board of several reputed journals (predominantly in Russia and Belarus). His Current Position is Head of Department of Gastroenterology and Nutrition, Byelorussian Medical Academy Postgraduate Education (BelMAPE). He is principal investigator on numerous clinical 18 and preclinical 6 studies and has been involved in the study of many medication including mesalazine, amino acids, anti-TNF.

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