Effect of pleuran (β-glucan from *Pleurotus ostreatus*) on the clinical course of patients with chronic rhinosinusitis.

EPCCOR study

SUMMARY OF STUDY PROTOCOL

Title of clinical research:	**E**ffect of **P**leuran (β-glucan from *Pleurotus Ostreatus*) on the **C**linical **C**ourse of Patients With Chr**o**nic **R**hinosinusitis.
Acronym:	EPCCOR
Principal investigators:	doc. MUDr. Milan Urík, Ph.D.[1], Phone: +420 532 234 440, Email: urik.milan@fnbrno.cz MUDr. Barbora Uhliarová, PhD., MPH[3] Phone: +421 48 441 2945, +421 911 499 084, Email: b.uhliarova@gmail.com
Investigators:	MUDr. Vít Kruntorád[1] MUDr. Petr Vaverka[2] MUDr. Karolína Hanulová[4] MUDr. Margaréta Lásková[5]
Investigating sites:	[1]Department of Pediatric ENT, University Hospital Brno - Children's Hospital, Černopolní 9, Brno, Czechia 613 00 [2]ORL department, University Hospital Brno, Jihlavská 25, Brno, Czechia 625 00 [3]ORL department, F.D. Roosevelt University Hospital with Policlinic, Banská Bystrica, Slovakia [4]ORL private practice – Sante s.r.o, Zdravomed 2, Cesta k nemocnici 1, Banská Bystrica, Slovakia [5]ORL private practice – ORL-HP s.r.o., Nemocničná – poliklinika 1, Veľký Krtíš, Slovakia
Study design:	Multicentre, prospective, randomized, open-label, controlled study with a dietary supplement Imunoglukan P4H® capsules in newly diagnosed patients over 12 years old with chronic rhinosinusitis without nasal polyps.
Project summary:	**Chronic rhinosinusitis** (CRS) is a serious and growing health issue. The quality of life of patients with CRS is, in some areas, even worse than that of patients with chronic heart failure, chronic obstructive pulmonary disease, or chronic back pain. A well-functioning immune system is essential for alleviating CRS symptoms and improving disease outcomes. Currently, there is no clinical study evaluating the effect of pleuran (β-glucan from *Pleurotus ostreatus*) in patients with CRS. The primary goal of this clinical research is to learn if Imunoglukan P4H® as an add-on therapy to standard of care treatment according to the EPOS guidelines can help to prevent CRS exacerbations, respiratory tract infections and reduce the use of antibiotics and intranasal corticosteroids

	(INCS) in newly diagnosed children over 12 years old age and adults with CRS without nasal polyps. The investigational product, Imunoglukan P4H® capsules, will be added to the standard of care treatment according to the EPOS guidelines (INCS and saline irrigation) as prescribed by their treating physician. Patients will be proportionally randomized into two arms: **Group A:** standard of care treatment with INCS and saline irrigation + Imunoglukan P4H® capsules (IMG® 100 mg + Vitamin C 100 mg) at a dose of 2 capsules once daily for 3 months, then there will be three months follow-up (without Imunoglukan P4H®). This cycle (3-month treatment and 3-month follow-up) will be repeated twice (only participants in the active group). **Group B:** standard of care treatment with INCS and saline irrigation
Study population:	Newly diagnosed patients over 12 years old with a diagnosis of chronic rhinosinusitis without nasal polyps meeting the inclusion criteria
Inclusion criteria:	• age over 12 years • signed informed consent • patients with newly diagnosed CRS without nasal polyps (meeting the criteria for the definition of CRS according to EPOS) • patients without anatomical abnormalities causing nasal obstruction (nasal septal deformity, nasal turbinate hyperplasia, tumours, craniofacial deformities) • patients able and willing to complete the questionnaires, undergo rhinoendoscopic examination, upper aerodigestive tract swabs and follow-up outpatient examinations
Exclusion criteria:	• refused informed consent • inability/unwillingness to complete the questionnaire, undergo rhinoendoscopic examination, upper aerodigestive tract swabs, follow-up outpatient examinations • inability/unwillingness to use the product in accordance with the research protocol and compliance < 75% • patients with protracted rhinosinusitis, exacerbations rhinosinusitis with the presence of an asymptomatic period • patients with CRS during conservative treatment • patients with CRS after previous surgical treatment • patients with grade 3 nasal polyps • patients with adenoid vegetations/persistent pharyngeal tonsils (especially if children are included in the study) • patients with CRS with anatomical abnormalities causing nasal obstruction (septal deformity, turbinate hyperplasia, tumors, craniofacial abnormalities) • patients with significant immunodeficiency • patients with mucociliary transport disorders (e.g. cystic fibrosis, primary ciliary dyskinesia)

	• patients taking other immunomodulating preparations regularly and for a long time (e.g. beta-glucans, Preventan, vitamins C and D, probiotics, Echinacea, bacterial lysates, etc.) • pregnant and breastfeeding women
Primary endpoints:	To evaluate the effect of Imunoglukan P4H® capsules as an add-on therapy to the standard of care treatment according to the EPOS guidelines in patients with CRS without nasal polyps on reduction of: • number of CRS exacerbations, • use of antibiotics, • use of intranasal corticosteroids, • incidence of respiratory tract infections.
Secondary endpoints:	To evaluate the effect of Imunoglukan P4H® capsules as an add-on therapy to the standard of care treatment according to the EPOS guidelines in patients with CRS without nasal polyps on: • severity of CRS, • subjective signs of CRS, • objective signs of CRS, • microbiological cultivation in the upper aerodigestive tract, • safety and tolerability
Number of Patients:	• **Czech republic:** 60 patients enrolled by investigators at 2 centres, randomized into active and control groups (30+30) • **Slovakia:** 100 patients enrolled by investigators at 3 centres, randomized into active and control groups (50+50)
Study Duration:	01.11. 2022 – 31.12. 2025