Real-life Study of Changes of Gastroesophageal Reflux Disease Manifestations Due to Behavioural and Diet Adherence

NCT04255693

Status	RECRUITING
Phase	Not Applicable
Sponsor	Federal State Budgetary Scientific Institution "Federal Research Centre of Nutrition, Biotechnology
Enrollment	150 participants

Key Eligibility Criteria

Inclusion (2)

- willingness to participate (based on the signed informed consent form);
- presence of gastroesophageal reflux disease, based on the following: a) typical symptoms, like heartburn and/or regurgitation (for primary selection, symptoms should be present at least weekly, be actual for at least 3 months prior to the enrolment, and the patient should report the history of symptoms which lasts for at least 6 months); b) previous response to the intake of proton pump inhibitors; c) data of 24-hours oesophageal pH-impedance monitoring with detected pathological gastroesophageal reflux according to the Lyon consensus definitions;

Exclusion (6)

- pregnant or breast-feeding females;
- abdominal or chest surgery (except appendectomy or cholecystectomy in case they are not followed by adhesive disease of the abdominal organs);
- constant use of non-steroidal anti-inflammatory agents (NSAIDs), sporadic use of NSAIDs will be allowed in case the course of treatment was discontinued at least 2 weeks prior to the enrolment, in case that constant use of NSAIDs happen to be necessary after the enrolment, the patients may continue in the study but doses, frequency and duration of treatment should be carefully documented;
- history or current evidence of cancer of any aetiology and location besides skin cancer in situ successfully treated before the enrolment;
- severe patient's conditions which may lead to misinterpretation of data, or in case of patient's enrolment may put him at risk of exacerbation of co-morbid conditions, or in cases when on discretion of the investigator patient's condition would not allow him to complete the course of the observation. These conditions include, but not limited to: heart failure (class III-IV by NYHA), uncontrolled hypertension, severe neurological disorders, decompensated liver cirrhosis (Child-Pugh B or C), severe depression or other psychological disorders;

... and 1 more (see full listing online)

Locations (1 total)

Federal State Budgetary Scientific Institution "Federal Research Centre of Nutrition, Biotechnology, Moscow, Russia