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Six food elimination diet in functional dyspepsia

Submission date
22/10/2025

Recruitment status
No longer recruiting

Registration date
16/01/2026

Overall study status
Completed

Last Edited
16/01/2026

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Functional dyspepsia is a common digestive condition that affects about 10 to 15 percent of people worldwide. It causes symptoms like bloating, stomach discomfort, feeling full quickly, and nausea, which can seriously affect quality of life. There is currently no cure. Some recent research suggests that certain foods might trigger an abnormal immune response in people with this condition. This study is investigating whether removing six specific foods—milk, wheat, soy, eggs, nuts, and seafood—from the diet for four weeks can help improve symptoms and provide useful biological information through blood, stool, and urine tests.

Who can participate?
Adults aged 18 and over who have been diagnosed with functional dyspepsia can take part. Healthy volunteers are also welcome. People cannot participate if they have active cancer, other digestive diseases like ulcers or inflammatory bowel disease, serious health conditions, are pregnant or breastfeeding, have known allergies to any of the six foods being removed, or have taken antibiotics or probiotics in the last three months.

What does the study involve?
Each participant will be involved for four weeks. At the start, they will have a medical check-up, complete symptom questionnaires, and provide blood, stool, and urine samples. Then, for four weeks, they will follow a diet that excludes milk, wheat, soy, eggs, nuts, and seafood. They can contact the study team by phone or email if needed. At the end of the four weeks, they will repeat the questionnaires and provide another set of samples. The team will also check that everything went safely.

What are the possible benefits and risks of participating?
Participants may experience relief from symptoms like bloating and nausea. The study may also help researchers better understand how diet affects this condition and could lead to more personalized dietary advice in the future. Risks are minimal. Changing the diet may be challenging and could temporarily worsen symptoms. Giving blood may cause minor discomfort or bruising. Overall, the diet is temporary and generally well tolerated.

Where is the study run from?
The study is being conducted at the Department of Internal Medicine – Gastroenterology, University Hospital Martin, Jessenius Faculty of Medicine, Comenius University, in Martin, Slovakia.

When is the study starting and how long is it expected to run for?

Who is funding the study?
Clinic of Internal Medicine-Gastroenterology, University Hospital Martin, Jessenius Faculty of Medicine in Martin, Comenius University, Slovakia.

Who is the main contact?
Dr Peter Liptak, peter.liptak@uniba.sk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
The impact of a six food elimination diet on clinical symptoms and metabolomic parameters in patients with functional dyspepsia compared to healthy volunteers

Acronym
FunDiet

Study objectives
Hypothesis: The six-food elimination diet alleviates symptoms of functional dyspepsia without inducing significant alterations in the individuals' metabolic profile.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 07/12/2022, Independent Ethics Committee at the Jessenius Faculty of Medicine, Comenius University in Martin (Department of Public Health Jessenius School of Medicine, Comenius University Malá Hora 4B, Martin, 036 01, Slovakia; +421 43 2633604; jana.mahutova@uniba.sk), ref: EK 72/2022

2. approved 28/06/2023, Independent Ethics Committee at the Jessenius Faculty of Medicine, Comenius University in Martin (Department of Public Health Jessenius School of Medicine, Comenius University Malá Hora 4B, Martin, 03601, Slovakia; +421 43 2633604; jana.mahutova@uniba.sk), ref: EK 38/2023

Study design
Single center interventional non randomised trial

Primary study design
Interventional

Study type(s)
Efficacy, Quality of life, Treatment

Health condition(s) or problem(s) studied
Patients with functional dyspepsia presenting with postprandial distress syndrome, epigastric pain syndrome, or an overlap of both subtypes

Interventions
Intervention type: Dietary modification
Intervention description: Implementation of a six-food elimination diet excluding dairy, wheat, soy, eggs, nuts, and seafood for 4 weeks.
Duration of intervention: 4 weeks (30 days)
Adherence support: Clinitian consultation, food diary

Intervention Type
Behavioural

Primary outcome(s)
Dyspeptic symptom burden assessed by validated questionnaires (PAGI-SYM, PHQ-15, PAGI-QoL, WHOQOL-BREF) at baseline and after 30 days of dietary intervention

Key secondary outcome(s))
Metabolic parameters from blood, urine, and stool (assessed by Nuclear Magnetic Resonance (NMR) spectroscopy metabolomic analysis) at baseline and after 30 days of dietary intervention

Completion date
31/12/2025

Eligibility

Key inclusion criteria
For patients:
1. Age ≥ 18 years
2. Diagnosed functional dyspepsia (Rome IV criteria)
3. Absence of acute somatic disease
4. Absence of chronic metabolic disease

For healthy volunteers:
1. Age ≥ 18 years
2. Absence of symptoms of DGBI
3. Absence of acute somatic disease
4. Absence of chronic metabolic disease

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Active malignancy (except long-term remission)
2. Severe metabolic or endocrine disease (e.g. decompensated diabetes, untreated hypothyroidism)
3. Pregnancy
4. Age < 18 years
5. Inability to attend follow-up visit

Date of first enrolment
05/02/2023

Date of final enrolment
01/12/2025

Locations

Countries of recruitment
Slovakia

Study participating centre
Clinic of Internal Medicine-Gastroenterology, University Hospital Martin, Jessenius Faculty of Medicine in Martin, Comenius University, Slovakia
Kollarova 2, 03601
Martin
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03601

Sponsor information

Organisation
Clinic of Internal Medicine-Gastroenterology, Jessenius Faculty of Medicine in Martin, Comenius University

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Clinic of Internal Medicine-Gastroenterology, University Hospital Martin, Jessenius Faculty of Medicine in Martin, Comenius University, Slovakia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the curret study will be available upon request from Peter Liptak (email:peter.liptak@uniba.sk)

IPD sharing plan summary
Available on request