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Consumption of ancient grain flours as a new therapeutic option for irritable bowel syndrome

Submission date
24/04/2025

Recruitment status
No longer recruiting

Registration date
13/06/2025

Overall study status
Completed

Last Edited
22/12/2025

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Climate change and its impact on food systems have renewed interest in sustainable crops like ancient grains, which offer environmental and nutritional benefits. Unlike modern cereals, ancient grains are less processed, more resilient to harsh conditions, and have a lower environmental footprint. Emerging evidence suggests that certain ancient grains, such as Triticum monococcum and Jermano wheat, may be better tolerated in individuals with irritable bowel syndrome (IBS) due to their lower fermentable oligosaccharides, disaccharides, monosaccharides and polyols (FODMAP) content and improved digestibility. This study investigates the potential of these grains in developing a functional pasta to manage IBS symptoms.

Who can participate?
Adult patients aged 18 years and over with a diagnosis of IBS

What does the study involve?
Participants are randomly allocated to the intervention group or the control group. The intervention group receives a low-FODMAP diet that includes the functional pasta (80 g, 4 times per week) for 4 weeks. The control group receive a low-FODMAP diet that includes gluten-free pasta (80 g, 4 times per week) for 4 weeks. Gastrointestinal symptoms, mood disturbances and quality of life will be assessed using validated clinical questionnaires at the start and the end of the study.

What are the possible benefits and risks of participating?
The potential benefit is an improvement in IBS symptoms. There are no risks for participants.

Where is the study run from?
University Magna Grecia (Italy)

When is the study starting and how long is it expected to run for?
Septemper 2022 to Septemper 2024

Who is funding the study?
University Magna Grecia (Italy)

Who is the main contact?
Prof. Tiziana Montalcini, tmontalcini@unicz.it

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Protocol serial number
279/2022/CE

Study information

Scientific Title
Ancient grain flours in IBS

Acronym
AGORA-IBS

Study objectives
The hypothesis is that the consumption of a functional pasta made from ancient grains will result in a significant reduction in symptom severity in patients with irritable bowel syndrome (IBS).

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 15/09/2022, Ethics Committee Calabria Region Central Area Section (Comitato Etico Regione Calabria Sezione Area Centro) (A.O.U. Mater Domini in Via Tommaso Campanella, 115, Catanzaro, 88100, Italy; +39 (0)961 712 111; comitatoetico@hotmail.it), ref: 279/2022/CE

Primary study design
Interventional

Study design
Randomized open-label clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Irritable bowel syndrome

Interventions
Participants will be enrolled after providing written informed consent and will be randomly assigned (by computer-generated random numbers) in a 1:1 ratio to one of two treatment groups:

Group 1: Patients following a low-FODMAP diet including the functional pasta (80 g, 4 times per week).

Group 2: Patients following a low-FODMAP diet including gluten-free pasta (80 g, 4 times per week).

Participants will be assessed using validated clinical questionnaires evaluating gastrointestinal symptoms.

Intervention Type
Supplement

Primary outcome(s)
Gastrointestinal symptoms measured using the Irritable Bowel Syndrome Symptom Severity Score (IBS-SSS) at baseline and after 4 weeks of treatment

Key secondary outcome(s)
The following secondary outcome measures are assessed at baseline and after 4 weeks of treatment:
1. Anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS)
2. Quality of life measured using the SF-36 scale (IQOLA SF-36 Italian version 1.6)

Completion date
17/09/2024

Eligibility

Key inclusion criteria

1. Age ≥ 18 years
2. Diagnosis of irritable bowel syndrome (IBS)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
42

Key exclusion criteria
1. Confirmed diagnosis of celiac disease or wheat allergy
2. Organic gastrointestinal disorders
3. Severe systemic conditions
4. Malnutrition
5. Psychiatric disorders
6. Adherence to specific dietary regimes
7. Pregnant or breastfeeding women

Date of first enrolment
17/03/2023

Date of final enrolment
26/07/2024

Locations

Countries of recruitment
Italy

Study participating centre
Nutrition Unit of the “R.Dulbecco” Azienda University Hospital
Viale Europa
Campus Universitario S. Venuta
Catanzaro

Italy
88100

Sponsor information

Organisation
Magna Graecia University

ROR
https://ror.org/0530bdk91

Funder(s)

Funder type
University/education

Funder Name
Magna Graecia University

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Tiziana Montalcini, tmontalcini@unicz.it.

The IPD that underlie the results reported in the main publication (including baseline data, primary outcomes, and secondary outcomes) will be made available after de-identification. The data will be accessible beginning 6 months after publication and for up to 5 years by researchers who provide a methodologically sound proposal. Data will be shared in accordance with participant consent and applicable ethical guidelines. A data-sharing agreement may be required.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/12/2025	22/12/2025	Yes	No
Participant information sheet	version 1.0	05/09/2022	29/04/2025	No	Yes