

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

Submission date 24/04/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/06/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/12/2025	Condition category Digestive System	<input type="checkbox"/> 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?

September 2022 to September 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

Prof Tiziana Montalcini

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

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

Study design

Randomized open-label clinical trial

Primary study design

Interventional

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 \geq 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	version 1.0	19/12/2025	22/12/2025	Yes	No
Participant information sheet		05/09/2022	29/04/2025	No	Yes

