ISRCTN12170245 https://doi.org/10.1186/ISRCTN12170245

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

Submission date 24/04/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 13/06/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 13/06/2025	**Condition category** Digestive System	[_] Individual participant data [X] Record updated in last year

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
Prof Tiziana Montalcini

ORCID ID
https://orcid.org/0000-0001-7048-5830

Contact details
Magna Graecia University
Viale Europa
Catanzaro
Italy
88100
+39 9613697314
tmontalcini@unicz.it

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

Secondary outcome measures
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)

Overall study start date
15/09/2022

Completion date
17/09/2024

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

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

Sponsor details
Viale Europa
Catanzaro
Italy
88100
+39 0961 3694001
protocollo@cert.unicz.it

Sponsor type
University/education

Website
https://web.unicz.it

ROR
https://ror.org/0530bdk91

Funder(s)

Funder type
University/education

Funder Name
Magna Graecia University

Results and Publications

Publication and dissemination plan
Publication in a journal in English with an impact factor, and in the mass media.

Intention to publish date
30/11/2025

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?
Participant information sheet	version 1.0	05/09/2022	29/04/2025	No	Yes