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Efficacy and safety of probiotics in the treatment of irritable bowel syndrome: a systematic review and meta-analysis of randomised clinical trials using ROME IV criteria V.1

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Giorgos Konstantis[1], Efstathiou Stylianos[2], Chryssa Pourzitaki[2], Kitsikidou Elisavet[3], Germanidis Georgios[4], Chourdakis Michail[5]

[1], Clinical Pharmacology, Faculty of Medicine, School of Health Sciences, Aristotle University of Thessaloniki, Thessaloniki, Greece and Department of Gastroenterology, Hepatology and Transplant Medicine, Medical Faculty, University of Duisburg-Essen, Essen, Germany.;
[2]Clinical Pharmacology, Faculty of Medicine, School of Health Sciences, Aristotle University of Thessaloniki, Thessaloniki, Greece.;
[3]Department of Internal Medicine, Evangelical Hospital Dusseldorf, Dusseldorf, Germany;
[4]Division of Gastroenterology and Hepatology, 1st Department of Internal Medicine, AHEPA University Hospital, School of Medicine, Faculty of Health Sciences, Aristotle University of Thessaloniki, Thessaloniki, Greece.;
[5]Laboratory of Hygiene, Social & Preventive Medicine and Medical Statistics, School of Medicine, Faculty of Health Sciences, Aristotle University of Thessaloniki, Thessaloniki, Greece.

G Giorgos Konstantis

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Protocol status: Working
We use this protocol and it's working

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Keywords: treatment of irritable bowel syndrome, patients with irritable bowel syndrome, irritable bowel syndrome, safety of probiotic, administration of probiotic, probiotics beneficial for patient, adults with irritable bowel syndrome, irritable bowel syndrome symptom severity score, dose of probiotic, probiotic, department of gastroenterology, gastroenterology, clinical pharmacology, constipation, diarrhea, type of ib, division of gastroenterology, ib, related clinical trial, clinical trial, using rome iv criteria systematic review, rome iv criteria systematic review, preventive medicine, efficacy, digestive system

Abstract

Systematic review

1. * Review title.

Efficacy and safety of probiotics in the treatment of irritable bowel syndrome: a systematic review and meta-analysis of randomised clinical trials using ROME IV criteria

2. * Anticipated or actual start date.

01 October 2021

3. * Anticipated completion date.

November 2022

4. * Stage of review at time of this submission.

competed

5. * Named contact.
Chryssa Pourzitaki, MSc, PhD

6. * Named contact email.
chpour@gmail.com

7. Named contact address

Chryssa Pourzitaki, Aristotle University of Thessaloniki, Thessaloniki, Greece

8. * Organisational affiliation of the review.

Aristotle University of Thessaloniki

9. * Review team members and their organisational affiliations.

Konstantis Georgios, Clinical Pharmacology, Faculty of Medicine, School of Health Sciences, Aristotle University of Thessaloniki, Thessaloniki, Greece and Department of Gastroenterology, Hepatology and Transplant Medicine,

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10. * Funding sources/sponsors.
None

11. * Conflicts of interest.
None

12. * Review question.

Are probiotics beneficial for patients with irritable bowel syndrome, diagnosed based on Rome IV criteria, in comparison with patients who are treated with placebo?

13. * Searches.

The electronic databases MEDLINE, SCOPUS, Cochrane DATABASE will be searched in order to identify appropriate studies. Furthermore, to find completed or ongoing studies without published data, we will examine reference lists from related clinical trials and systematic reviews, and specific websites (clinicaltrials.gov, controlled-trials.com, nyam.org) will be also searched. No time restrictions on the publication date of the studies will be applied. Reference lists from the included studies and systematic reviews will be identified and hand-searched for relevant randomised clinical trials.

14. * Condition or domain being studied.

Irritable bowel syndrome. Benefit and safety of probiotics.

15. * Participants/population.

Inclusion criteria: Adults with irritable bowel syndrome using Rome IV criteria and studies that reported data for at least one of the outcomes of interest,
Exclusion criteria: Patients under 18 years old and patients who don't fulfill the Rome IV criteria

16. * Intervention(s), exposure(s).

Patients with Irritable Bowel Syndrome (IBS) complain about diarrhea, constipation and abdominal pain. These symptoms often worsen the quality of life. The majority of clinicians administrate various drug therapies. We will examine if the administration of probiotics is beneficial for IBS- patients and improve the symptoms and quality of life.

17. * Comparator(s)/control.

Patients with irritable bowel syndrome according to Rome IV criteria who receive placebo

18. * Types of study to be included.

Randomised Controlled Trials with placebo control

19. * Main outcome(s).

Irritable Bowel Syndrome Symptom Severity Score (IBS-SSS), abdominal pain
Measures of effect: Weighted Mean Difference (WMD), Standardized Mean Difference (SMD)

20. * Additional outcome(s).

Quality of life, bloating, adverse effects
Measures of effect: SMD 95% CI

21. * Data extraction (selection and coding).

Articles retrieved from the whole of the literature will be inserted into an electronic reference manager (Endnote19) and will be examined by two independent reviewers. Duplicated articles will be removed, and any discrepancies will be resolved with the help of a third reviewer. Data extraction related to year of publication, follow-up period, country of origin, the type of study, the characteristics of patients (sex, age), the type and dose of probiotics, the type of IBS and primary and secondary outcomes will be performed, with the help of a prespecified form, also from two independent reviewers. For cross-over trials only data from the first period will be extracted in an attempt to diminish a possible carry over effect. An available cases approach will be implemented, and participants excluded from analysis will be treated as to be missing at random. Regarding adverse effects, data from maximum follow up period will be evaluated.

22. * Risk of bias (quality) assessment.

Risk of bias assessment using the Cochrane Risk of Bias tool (ROB) 2.0 for all eligible studies will be implemented. The assessment will be conducted for 5 domains which are randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome and selection of the reported result. The risk of each domain will be examined as “low”, “high” and “some concerns” and studies evaluated as high risk for a single category will be considered to have high overall risk of bias.

23. * Strategy for data synthesis.

Continuous data will be synthesized by calculating the weighted mean difference (WMD) and 95% confidence intervals (CIs) with the help of DerSimonian-Laird estimation method, when all studies used the same method for expressing the outcome of interest. Hedges’g estimation method will be used when different scales were used by the individual studies and in this case the results will be expressed as standardized mean difference (SMD).

Between study heterogeneity will be explored with the use of Cochran’s Q and will be quantified with the use of I2 statistic, according to which more than 60% correlates with high heterogeneity. All statistical analyses will be performed using STATA SE, version 16.1 (Stata Corp) using the “meta” suite of commands.

24. * Analysis of subgroups or subsets.

Sensitivity analyzes will be performed considering each study's risk of bias and statistical assumptions and techniques that may be used during data extraction to establish the robustness of our results. Subgroup analysis will take into consideration the presence or absence of a low FODMAP diet

25. * Type and method of review.

Type of review

Meta-analysis

Health area of the review

Digestive system

26. * Country.
Greece

27. Dissemination plans.

Do you intend to publish the review on completion? Yes

28. Keywords.

Meta-analysis, Irritable Bowel Syndrome (IBS), Rome IV, probiotics, IBS- Symptom Severity Score, abdominal pain, bloating, quality of life

29. * Current review status.
Completed but not published

Troubleshooting

1

2 Systematic review

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Meta-analysis
Health area of the review
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  Greece
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Do you intend to publish the review on completion? Yes

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