

# INPLASY

## Efficacy and Safety of Probiotic-supplemented Bismuth Quadruple Therapy for Eradication of *Helicobacter Pylori*

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### ADMINISTRATIVE INFORMATION

**Support - No.**

**Review Stage at time of this submission - Completed but not published.**

**Conflicts of interest - None declared.**

**INPLASY registration number:** INPLASY202370051

**Amendments -** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 July 2023 and was last updated on 13 July 2023.

### INTRODUCTION

**Review question / Objective** The aim of this meta-analysis was to examine whether adding probiotics to the bismuth quadruple therapy for *Helicobacter pylori* could improve the eradication rate and reduce side effects.

**Condition being studied** Although classic or modified bismuth quadruple therapy (BQT) has a good performance in eradication of *Helicobacter pylori* (HP), poor tolerance and adverse reactions are reported as main reasons for discontinuation of BQT. Higher eradication rate and lower side effects rate are pursued. Probiotics may enhance the eradication rate and improve compliance by reducing side effects. To date, several trials have demonstrated the value of probiotics supplementation, while some trials reported opposite outcomes. A high quality meta-analysis of related randomized controlled trials that focuses the eradication rates and side effects of probiotics supplementation in BQT is urgent to perform.

### METHODS

**Participant or population** Patients with *Helicobacter pylori* infection.

**Intervention** Bismuth quadruple therapy plus probiotics.

**Comparator** Bismuth quadruple therapy with placebo or without extra interventions.

**Study designs to be included** Only randomized controlled trials were included.

**Eligibility criteria** Infection or eradication of *Helicobacter pylori* was confirmed by at least one generally accepted method. Studies compared at least two groups consisting of experimental patients receiving bismuth quadruple therapy (BQT) plus probiotics and control patients who underwent BQT treatment with placebo or without extra interventions. Studies were published in English. Trials were limited to human only. Full text articles in electronic version were available.

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**Information sources** Pubmed, Embase, Web of Science and The Cochrane Central Register of Controlled Trials.

**Main outcome(s)** Helicobacter pylori eradication rate and incidences of total side effects.

**Quality assessment / Risk of bias analysis** The assessment of risk of bias was conducted in accordance with the guideline of the Cochrane Collaboration. Random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias were assessed. Two reviewers categorized each entry into one of three levels (high, low or unclear risk). Consensus was reached by discussion.

**Strategy of data synthesis** For all outcomes in our analyses, pooled risk ratio (RR) with their corresponding 95% confidence intervals (CIs) were calculated using the Mantel-Haenszel random-effects model for dichotomous variables and presented as Forest plots. The possibility of publication bias was assessed by constructing a funnel plot if included studies were more than 10. Begg and Egger tests were also used to assess funnel plot asymmetry and P value 50% and P value < 0.1 indicated the presence of significant heterogeneity.

**Subgroup analysis** No.

**Sensitivity analysis** Sensitivity analysis was not performed because of no significant heterogeneity in primary outcome of eradication rate across the included studies.

**Country(ies) involved** China.

**Keywords** helicobacter pylori; probiotics; bismuth quadruple therapy; eradication; side effects.

#### **Contributions of each author**

Author 1 - Gaoyan Yao.

Author 2 - Xiaoyuan Fan.

Author 3 - Dewen Lu.