

# INPLASY PROTOCOL

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None declared.

## The effect of berberine on *Helicobacter pylori* eradication: a protocol for systematic review and meta analysis

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**Review question / Objective:** To assess the efficacy and safety of berberine on *Helicobacter pylori* eradication.

**Condition being studied:** *Helicobacter pylori* (*H. pylori*) is classified as class I carcinogens by the world health organization. Although eradication therapy is effective, there are significant adverse effects and more importantly, resistance to antibiotics occurs, which represents a major therapeutic challenge. A growing number of clinical controlled studies have found that berberine can improve the eradication rate of *H. pylori* and reduce the incidence of adverse reactions. However, there is still uncertainty about its safety and efficacy. Therefore, we plan to assess the efficacy and safety of berberine on *Helicobacter pylori* eradication.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 March 2022 and was last updated on 28 March 2022 (registration number INPLASY202230160).

### INTRODUCTION

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organization. Although eradication therapy is effective, there are significant adverse effects and more importantly, resistance to antibiotics occurs, which represents a major therapeutic challenge. A growing number of clinical controlled studies have found that berberine can improve the eradication rate of *H. pylori* and reduce the incidence of adverse reactions. However,

there is still uncertainty about its safety and efficacy. Therefore, we plan to assess the efficacy and safety of berberine on *Helicobacter pylori* eradication.

## METHODS

**Search strategy:** We will search the following databases from inception to January 2022: PubMed, MEDLINE, EMBASE, The Cochrane Library, Web of Science, Chinese National Knowledge Infrastructure database (CNKI), Chinese Scientific Journal database (VIP), Wan Fang database, and the Clinical.gov website. We also will search journal articles, conference papers, and academic papers.

**Participant or population:** The subjects included will be *H. pylori* positive patients.

**Intervention:** The intervention measures in the treatment group will be berberine used alone or combined with *Helicobacter pylori* eradication therapy.

**Comparator:** Just *Helicobacter pylori* eradication therapy without berberine.

**Study designs to be included:** Randomized controlled trials (RCTs).

**Eligibility criteria:** The subjects enrolled were adults with *H. pylori* infection with/without *H. pylori*-related disease including functional dyspepsia, gastritis and ulcers. The diagnosis of *H. pylori* infection was based on positive histology, rapid urease tests (RUT), urease breath tests (UBT), or *H. pylori* stool antigen test (HpSAg). The subjects included will be *H. pylori* positive patients.

**Information sources:** PubMed, Embase, The Cochrane Library, Web of Science, Medline, Chinese National Knowledge Infrastructure database (CNKI), Chinese Scientific Journal database (VIP), Wan Fang database.

**Main outcome(s):** Eradication rate of *H. pylori* after treatment.

**Additional outcome(s):** Incidence rate of adverse event.

**Quality assessment / Risk of bias analysis:** Two authors will independently evaluate the risk of bias of each included article on the basis of the Cochrane Handbook for Systematic Reviews of Interventions. The methodologic quality will be appraised from the following seven aspects: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessments, incomplete outcome data, selective reporting, and other bias. The risks will be categorized as low, high or unclear displaying in graphical form.

**Strategy of data synthesis:** We will use the RevMan software (v.5.3.0) for meta-analysis and statistical analysis. For dichotomous data, we plan to present results as risk ratio (RR) with 95% confidence intervals (CIs). For continuous data, we will use mean difference (MD) with 95% confidence intervals (CIs).

**Subgroup analysis:** If the necessary data are available, subgroup analyses will be done for people with different dose of berberine.

**Sensitivity analysis:** The stability of the meta-analysis results was tested through a one-by-one elimination method in sensitivity analysis.

**Country(ies) involved:** China.

**Keywords:** berberine, *Helicobacter pylori* eradication, protocol, meta analysis

### Contributions of each author:

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