TCTR ID : TCTR20260417013

OTHER ID :

Overall Recruitment Status : Completed **(No Results)**

Retrospective registration
This protocol was registered after enrollment of the first participant.

Tracking Information

First Submitted Date :	16 April 2026
First Posted Date :	17 April 2026
Last Update Posted Date :	16 April 2026

Title

Public Title :	Impact of Different Domperidone Dosages on Reflux Esophagitis Treated with Esomeprazole: A Randomized Controlled Trial
Acronym :	No Data
Scientific Title :	Impact of Different Domperidone Dosages on Reflux Esophagitis Treated with Esomeprazole: A Randomized Controlled Trial
Sponsor ID/ IRB ID/ EC ID :	ZXYEC-KT-2021-44-P03
Registration Site :	Thai Clinical Trials Registry
URL :	https://www.thaiclinicaltrials.org/show/TCTR20260417013
Secondary ID :	No Secondary ID

Ethics Review

1. Board Approval :	Submitted, approved
Approval Number :	ZXYEC-KT-2021-44-P03
Date of Approval :	20 November 2021
Board Name :	Ethics Committee of Beijing Hospital of Integrated Traditional Chinese and Western Medicine
Board Affiliation :	Beijing Hospital of Integrated Traditional Chinese and Western Medicine
Board Contact :	Business Phone : 0108822938 Ext. No Data
	Business Email : zxyxck@163.com
	Business Address : No. 86, Yongding Road, Haidian District, Beijing, China

Sponsor

Source(s) of Monetary or Material Supports :	Beijing Hospital of Integrated Traditional Chinese and Western Medicine Scientific Research Cultivation Project
Study Primary Sponsor :	Beijing Hospital of Integrated Traditional Chinese and Western Medicine
Responsible Party :	Name/Official Title : Ye Zhao
	Organization : Beijing Hospital of Integrated Traditional Chinese and Western Medicine
	Phone : 15801209500 Ext. No Data
	Email : Zhaoye9500@163.com
Study Secondary Sponsor :	No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis :	This single-center, prospective, randomized, controlled trial investigates 8-week treatment with esomeprazole (ESM) alone versus ESM plus three domperidone (DOM) doses in adults aged >18 years with endoscopy-confirmed reflux esophagitis (LA B-D); 376 patients were randomized 1:1:1:1 into control (ESM 40 mg qd), low-dose (ESM+DOM 5 mg tid), medium-dose (ESM+DOM 10 mg tid), and high-dose (ESM+DOM 15 mg tid) groups, with all medications given 30 minutes before meals plus standardized lifestyle advice. At baseline and week 8, assessments include endoscopy (primary endpoint: endoscopic remission rate, LA 0/A), esophageal manometry, 24-hour impedance-pH monitoring, serum inflammatory cytokines, symptom and quality-of-life scores; adverse events are recorded at weeks 4 and 8 under independent DSMB oversight, with blinded outcome assessors and electronic adherence monitoring.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied :	Reflux Esophagitis
Keywords :	Esomeprazole; Reflux esophagitis; Domperidone; Proton pump inhibitors

Eligibility

Inclusion Criteria :	(1) Have good compliance with the prescribed treatment and follow-up procedures; (2) Agreed to participate in this study and signed the informed consent; (3) Meet the above-mentioned diagnostic criteria for RE; (4) Aged > 18 years.
Gender :	Both
Age Limit :	Minimum : 18 Years Maximum : 50 Years
Exclusion Criteria :	(1) gastrointestinal bleeding, malignant tumor, long-segment Barrett's esophagus, esophageal stricture, esophageal varices, endoscopically confirmed esophageal stricture, or eosinophilic esophagitis; (2) a history of gastrointestinal surgery (apart from endoscopic resection); (3) an allergy to antacids or PPIs; (4) Malignant tumor history within the previous five years; (5) Patients with severe respiratory, central nervous, endocrine, or cardiovascular system diseases; (6) Having diseases of the liver or kidneys that are clinically important; (7) Women who are pregnant or nursing; (8) Those who have a history of mental illness; (9) Those who intend to be hospitalized or have surgery during the study period.
Accept Healthy Volunteers :	No

Status

Overall Recruitment Status :	Completed	
Key Trial Dates	Study Start Date (First enrollment) : 01 January 2022	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 31 December 2024	Indicate Type : Actual
	Study Completion Date : 31 December 2024	Indicate Type : Actual

Design

Study Type :	Interventional
Primary Purpose :	Treatment
Study Phase :	Phase 0
Intervention Model :	Parallel
Number of Arms :	4
Masking :	Open Label
Allocation :	Randomized
Control :	Dose Comparison
Study Endpoint Classification :	Efficacy Study
Sample size	
	Planned sample size : 361
	Actual sample size at study completion : 361
Intervantion Arm 1	
	Intervention name : control group
	Intervention Type : Active Comparator
	Intervention Classification : Drug
	Intervention Description : The standard esomeprazole (Astrazeneca, National Drug Approval No. H20046380, 40mg per tablet) treatment is administered at a dose of 40mg once daily, 30 minutes before meals, for a course of 8 weeks
Intervantion Arm 2	
	Intervention name : low-dose group
	Intervention Type : Experimental
	Intervention Classification : Drug
	Intervention Description : Patients were treated with different doses of domperidone (Sichuan Weiao Pharmaceutical, National Drug Approval No. H20093491, 10mg per tablet), 5mg (half a tablet), three times a day, 30 minutes before meals, for a course of 8 weeks
Intervantion Arm 3	
	Intervention name : medium-dose group
	Intervention Type : Experimental
	Intervention Classification : Drug
	Intervention Description : Patients were treated with different doses of domperidone (Sichuan Weiao

Pharmaceutical, National Drug Approval No. H20093491, 10mg per tablet), 10mg (one tablet), three times a day, 30 minutes before meals, for a course of 8 weeks

Intervantion Arm 4

Intervention name : high-dose group

Intervention Type : Experimental

Intervention Classification : Drug

Intervention Description : Patients were treated with different doses of domperidone (Sichuan Weiao Pharmaceutical, National Drug Approval No. H20093491, 10mg per tablet), 15mg (one and a half tablets), three times a day, 30 minutes before meals, for a course of 8 weeks

Outcome

Primary Outcome

1. Outcome Name : endoscopic remission rate

Metric / Method of measurement : Endoscope

Time point : at 8-week

Secondary Outcome

1. Outcome Name : symptom scores

Metric / Method of measurement : Gastroesophageal Reflux Disease Questionnaire

Time point : before and after treatment

2. Outcome Name : quality of life

Metric / Method of measurement : GERD-Health Related Quality of Life (GERD-HRQL) scale

Time point : before and after treatment

Location

Section A : Central Contact

Central Contact	First Name : Ye	Middle Name :	Last Name : Zhao
	Degree :	Phone : 15801209500 Ext. : No Data	Email : Zhaoye9500@163.com
Central Contact Backup	First Name : Wencui	Middle Name :	Lastname : Niu
	Degree :	Phone : 15810058031 Ext. : No Data	Email : xuege681230@163.com

Section B Facility Information and Contact

1. Site Name : Beijing Hospital of Integrated Traditional Chinese and Western Medicine

	City : Beijing	State/Province : Beijing	Postal Code : 100039
	Country : China	Recruitment Status : Completed	
Facility Contact	First Name : Ye	Middle Name :	Last Name : Zhao
	Degree :	Phone : 15801209500 Ext. : No Data	Email : Zhaoye9500@163.com
Facility Contact Backup	First Name : Wencui	Middle Name :	Last Name : Niu
	Degree :	Phone : 15810058031 Ext. : No Data	Email : xuege681230@163.com
Investigator Name	First Name : Ye	Middle Name :	Last Name : Zhao
	Degree :	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

First Name : Ye	Middle Name :	Last Name : Zhao
Degree : No Data	Phone : 15801209500 Ext. : No Data	Email : Zhaoye9500@163.com
Postal Address : No. 86, Yongding Road, Haidian District, Beijing, China		
State/Province : Beijing	Postal Code : 100039	
Country : China	Official Role : Study Principal Investigator	
Organization Affiliation : Beijing Hospital of Integrated Traditional Chinese and Western Medicine		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Ye	Middle Name :	Last Name : Zhao
Degree : No Data	Phone : 15801209500 Ext. : No Data	Email : Zhaoye9500@163.com
Postal Address : No. 86, Yongding Road, Haidian District, Beijing, China		
State/Province : Beijing	Postal Code : 100039	
Country : China	Official Role : Study Principal Investigator	

Organization Affiliation : Beijing Hospital of Integrated Traditional Chinese and Western Medicine

Summary Results

Date of posting of results summaries : Summary results not yet available

Date of first journal publication of results : Not yet published

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : No

Reason : The individual de-identified participant data collected in this study contain sensitive clinical information and are not publicly available due to ethical restrictions.

Publication from this study

MEDLINE Identifier : No Data

URL link to full text publication : No Data