

# Therapeutic study of the proton- pump inhibitors resistant patients with Non-Erosive Reflux Disease

<b>Submission date</b> 28/06/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/10/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/07/2021	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Kyoichi Adachi

**Contact details**  
Enya-cho 89-1  
Izumo-shi  
Japan  
693-8501

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**

Therapeutic study of the proton- pump inhibitors resistant patients with Non-Erosive Reflux Disease

**Acronym**

Rebamipide for NERD

**Study objectives**

Although half of the NERD patients who received Proton-Pump Inhibitors (PPI) for 4 weeks do not show their symptoms reduced, there is no standard therapy for these PPI-resistant patients. The esophageal mucosa of PPI-resistant NERD patients is hypersensitive to acid and histological damage may have occurred. Meanwhile, rebamipide is a gastro-protective agent and its antiinflammatory effect may improve histological damage of PPI-resistant NERD patients.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approval received from the ethics board of the Shimane University on the 29th April 2007.

**Study design**

Double-blind, randomized, placebo-controlled study.

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Non-Erosive Reflux Disease (NERD)

**Interventions**

After being treated with lansoprazole 15 mg/day for 4 weeks, the NERD patients who do not show reduction in their symptoms (more than 6 points diagnosed by the QUEST questionnaire or below 50% improvement diagnosed by the Gastroesophageal Reflux Symptoms [GERS] score) will then be randomly allocated to the intervention or control group:

Intervention group: 100 mg rebamipide orally three times a day (t.i.d) for 4 weeks

Control group: Placebo tablet (t.i.d) for 4 weeks

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Rebamipide

**Primary outcome measure**

The subjective symptoms are assessed by the Japanese version QUEST and Gastrointestinal Symptom Rating Scale (GSRS). The assessment by GSRS is limited to upper gastrointestinal tract questions. These will be measured at baseline, 1 month after PPI therapy and 1 month after repamipide or placebo.

**Secondary outcome measures**

Number of patients who complete the study protocol.

**Overall study start date**

01/06/2007

**Completion date**

31/12/2007

**Eligibility****Key inclusion criteria**

1. Aged 20 and over
2. Heartburn (more than 6 points diagnosed by the Japanese version of questionnaire for the diagnosis of reflux disease [QUEST])
3. Signed a study-specific informed consent form

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

80

**Total final enrolment**

149

**Key exclusion criteria**

1. Endoscopic esophagitis
2. Gastric and duodenal ulcers, stomach cancer, or acute gastritis
3. Known hypersensitivity to rebamipide
4. Catastrophic complications

- 5. Pregnancy or desire to become pregnant
- 6. Judged inappropriate for this study by the physicians

**Date of first enrolment**

01/06/2007

**Date of final enrolment**

31/12/2007

## Locations

**Countries of recruitment**

Japan

**Study participating centre**

Enya-cho 89-1

Izumo-shi

Japan

693-8501

## Sponsor information

**Organisation**

Shimane University, Second Department of Internal Medicine (Japan)

**Sponsor details**

Enya-cho 89-1

Izumo-shi

Japan

693-8501

**Sponsor type**

University/education

**ROR**

<https://ror.org/01jaaym28>

## Funder(s)

**Funder type**

University/education

**Funder Name**

Shimane University Hospital (Japan)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>			19/07/2021	Yes	No