

# 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
<b>Registration date</b> 11/10/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/07/2021	<b>Condition category</b> Digestive System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

## 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.

### **Primary study design**

Interventional

### **Study design**

Double-blind, randomized, placebo-controlled study.

### **Study type(s)**

Treatment

### **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(s)**

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.

### **Key secondary outcome(s)**

Number of patients who complete the study protocol.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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)

### ROR

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

## Funder(s)

### Funder type

University/education

### Funder Name

Shimane University Hospital (Japan)

## Results and Publications

### 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