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

Submission date 28/06/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/10/2007	**Overall study status** Completed	
Last Edited 19/07/2021	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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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?
Results article			19/07/2021	Yes	No