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# The effect of rebamipide for healthy subjects with Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)-induced small-intestinal injury: a prospective, randomised, double-blinded, placebo-controlled study

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| **Submission date**<br>11/07/2007 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>26/07/2007 | **Overall study status**<br>Completed | |
| **Last Edited**<br>27/04/2011 | **Condition category**<br>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**

218044

# Study information

## Scientific Title

## Study objectives
To evaluate the prevention by rebamipide and placebo of Non-Steroidal Anti-Inflammatory Drug (NSAID)-induced small-intestinal injury in healthy subjects.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
This trial was approved by Nippon Medical School ethical committee on the 28th March 2007.

## Study design
Double blind, randomised, placebo-controlled study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Prevention

## Participant information sheet

## Health condition(s) or problem(s) studied
Non-Steroidal Anti-Inflammatory Drug (NSAID)-induced small-intestinal injury

## Interventions
Rebamipide group: rebamipide 300 mg, diclofenac 75 mg and omeprazole 20 mg every day, thrice daily (t.i.d.) for two weeks
Placebo group: placebo, diclofenac 75 mg and omeprazole 20 mg every day, t.i.d. for two weeks

The subjects will be assigned to either rebamipide group or placebo group prior to the study. All medications will be taken orally. Final evaluation was done by capsule endoscopy at two weeks.

## Intervention Type
Drug

## Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Rebamipide

### Primary outcome measure
To evaluate the preventive effect of rebamipide for NSAIDs-induced small-intestinal mucosal brakes, evaluated by capsule endoscopy at time-course of day 0 and day 14.

### Secondary outcome measures
To evaluate the preventive effect of rebamipide for NSAIDs-induced small-intestinal slight injuries, such as erythema and petechiae, evaluated by capsule endoscopy at time-course of day 0 and day 14.

### Overall study start date
17/07/2007

### Completion date
30/06/2008

## Eligibility

### Key inclusion criteria
1. Male sex
2. Aged at least 20 years
3. Body Mass Index (BMI) 18.5 - 25 kg/m^2
4. Lack of history of GastroIntestinal (GI) disorder
5. Japanese population
6. Healthy on examination by a physician
7. Subject able to comprehend and give informed consent for participation in this study
8. Signed informed consent form

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Male

### Target number of participants
72

### Key exclusion criteria
1. Active gastrointestinal disease
2. Use of ulcerogenic medications within two weeks before starting the study
3. Prior gastric or intestinal surgery
4. Pregnancy

5. Physician objection
6. Concurrent participation in any other clinical trial

### Date of first enrolment
17/07/2007

### Date of final enrolment
30/06/2008

## Locations

### Countries of recruitment
Japan

### Study participating centre
**2-9,Kanda Tukasa-cho Chiyoda-ku**
Tokyo
Japan
101-8535

## Sponsor information

### Organisation
Individual Sponsor (Japan)

### Sponsor details
Dr Syunji Fujimori
2-9,Kanda Tukasa-cho Chiyoda-ku
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### Sponsor type
Other

## Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Nippon Medical School (Japan) - covering the incidental costs of running this trial

# 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 | results | 01/03/2011 | | Yes | No |