

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

Submission date 11/07/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 26/07/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/04/2011	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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.

Primary study design

Interventional

Study design

Double blind, randomised, placebo-controlled study

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s)

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.

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/m²
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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Male

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)

Funder(s)

Funder type
Hospital/treatment centre

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

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?
Results article	results	01/03/2011		Yes	No