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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

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

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
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Sponsor information

Organisation
Individual Sponsor (Japan)

Sponsor details
Dr Syunji Fujimori
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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