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Eradication of Helicobacter pylori increases ghrelin production in the gastric mucosa

Submission date	Recruitment status	[_] Prospectively registered
15/02/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/03/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/08/2011	Infections and Infestations	[_] Record updated in last year

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

Study objectives
To investigate whether Helicobacter pylori eradication influences ghrelin/obestatin production and appetite.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of Inje University, Ilsan-Paik Hospital, Clinical Research Center 05-12, South Korea. Date of approval: 28/10/2005

Study design
Randomised controlled trial

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
Helicobacter pylori infection

Interventions
The treatment group received a triple H. pylori eradication regimen consisting of 20 mg esomeprazole, 1,000 mg amoxicillin and 500 mg clarithromycin, twice daily for 7 days. The control group received no medication.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
esomeprazole, amoxicillin, and clarithromycin

Primary outcome measure
Ghrelin mRNA levels in gastric mucosa at baseline and 5 weeks

Secondary outcome measures
The following were assessed at baseline and 5 weeks:
1. Obestatin and TNF-a mRNA of gastric mucosa
2. Plasma ghrelin, obestatin and ghrelin/obestatin ratio

Overall study start date
17/02/2006

Completion date
30/05/2006

Eligibility

Key inclusion criteria
Healthy volunteers with H. pylori infection, who saw a poster describing the study and wanted to participate.

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Age <20 or >70 years
2. Pregnancy
3. Abnormal gastric lesion, including ulcer and cancer
4. Duodenal ulcer
5. Liver disease
6. Renal impairment
7. Previous gastrointestinal surgery
8. History of H. pylori eradication
9. Drug abuse

Date of first enrolment
17/02/2006

Date of final enrolment
30/05/2006

Locations

Countries of recruitment
Korea, South

Study participating centre
2240
Gyeonggi-do
Korea, South
411-706

Sponsor information

Organisation
Inje University, Ilsan Paik Hospital (Korea, South)

Sponsor details
2240
Daewha-dong
Ilsanseo-gu
Goyang-si
Gyeonggi-do
Korea, South
411-706

Sponsor type
University/education

Website
http://www.inje.ac.kr/english

ROR
https://ror.org/01zx5ww52

Funder(s)

Funder type
University/education

Funder Name
Inje University, Ilsan paik Hospital (Korea, South)

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