

Eradication of *Helicobacter pylori* increases ghrelin production in the gastric mucosa

Submission date 15/02/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/03/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/08/2011	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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411-706

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- α 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