ISRCTN01756929 https://doi.org/10.1186/ISRCTN01756929

Mastic Gum and Helicobacter Pylori eradication: an in vivo pilot study

Submission date	Recruitment status	[_] Prospectively registered
31/03/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/04/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/09/2010	Infections and Infestations	

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
MGHP05

Study information

Scientific Title

Acronym
MGHP

Study objectives
Mastic gum is effective in eradicating Helicobacter pylori in vivo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Greek Medicines Agency Ethics Board on the 18th December 2005 (ref: MGCGH0032/06).

Study design
Randomised controlled trial with three arms

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Helicobacter pylori gastritis

Interventions
Patients positive to Helicobacter pylori will be randomised to receive one of the following:

1. Mastic gum 2 g per day for 14 days
2. Mastic gum 2 g per day and pantoprazole 40 mg per day for 14 days
3. Pantoprazole 40 mg per day, amoxicillin 2 g per day and clarithromycin 1 g per day for 10 days

Follow up was two months after the end of the treatment for all study arms.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Mastic gum, pantoprazole, amoxicillin, clarithromycin

Primary outcome measure
Eradication of Helicobacter pylori, measured at five weeks after the end of treatment.

Secondary outcome measures
Helicobacter pylori load in patients remaining H. pylori positive, measured at five weeks after the end of treatment.

Overall study start date
01/12/2006

Completion date
01/06/2007

Eligibility

Key inclusion criteria
1. Patients tested positive for H. pylori
2. Adults of either sex aged between 18 and 75 years of age

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
42

Key exclusion criteria
1. Pregnancy
2. Malignancy
3. Allergies to pantoprazole, amoxicillin, clarithromycin

Date of first enrolment
01/12/2006

Date of final enrolment
01/06/2007

Locations

Countries of recruitment
Greece

Study participating centre
Helenas Venizelou 2
Chios
Greece
821-00

Sponsor information

Organisation
The Chios Mastic Gum Producers Cooperative (Greece)

Sponsor details
Konstantinou Monomahou 1
Chios
Greece
821-00

Sponsor type
Industry

Website
http://www.gummastic.gr

ROR
https://ror.org/05rpby975

Funder(s)

Funder type
Industry

Funder Name
The Chios Mastic Gum Producers Cooperative (Greece)

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	01/03/2010		Yes	No