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

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

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Konstantinos Dabos

#### Contact details

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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