Evaluation of Effectiveness of Mastic Gum in Functional Dyspepsia

| Submission date | Recruitment status No longer recruiting | [X] Prospectively registered | | |
|------------------------------|---|--------------------------------|--|--|
| 18/04/2007 | | ☐ Protocol | | |
| Registration date 30/04/2007 | Overall study status Completed | Statistical analysis plan | | |
| | | [X] Results | | |
| Last Edited | Condition category | [] Individual participant data | | |
| 09/02/2010 | Digestive System | | | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers MGCGH0031

Study information

Scientific Title

Acronym

EEMGFD

Study objectives

Mastic gum improves symptoms in functional dyspepsia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the North Aegean scientific research committee in October 2006 (ref: 165/06).

Study design

Prospective randomised double blind placebo controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Functional dyspepsia

Interventions

Patients will be given either pure mastic gum in capsule form containing 350 mg or placebo capsules, twice daily. Patients will have treatment for three weeks. For safety reasons there will be a follow up visit four weeks later.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

- 1. Total symptom score changes, measured once at the end of treatment.
- 2. Global assessment of symptoms, measured once at the end of treatment.

Secondary outcome measures

Individual symptom changes, measured once, at the end of treatment.

Overall study start date

01/05/2007

Completion date

01/08/2008

Eligibility

Key inclusion criteria

- 1. Rome II criteria for functional dyspepsia
- 2. Negative Helicobacter pylori status
- 3. Negative gastroduodenoscopy

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

140

Key exclusion criteria

- 1. Primarily symptoms of Gastro-Oesaphageal Reflux Disease (GORD)
- 2. On prokinetic drugs
- 3. Suffering from Gastrointestinal (GI) malignancy

Date of first enrolment

01/05/2007

Date of final enrolment

01/08/2008

Locations

Countries of recruitment

Greece

Study participating centre

Demokratias 5

Chios Greece 821-00

Sponsor information

Organisation

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

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 summaryNot provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 03/02/2010 | | Yes | No |