

Evaluation of Effectiveness of Mastic Gum in Functional Dyspepsia

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Konstantinos Dabos

Contact details
Demokratias 5
Chios
Greece
821-00
+30 2271 028 729
kostasophia@yahoo.com

Additional identifiers

Protocol serial number
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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Primarily symptoms of Gastro-Oesophageal 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)

ROR

<https://ror.org/05rpby975>

Funder(s)

Funder type

Industry

Funder Name

Mastic Gum Producers Cooperative (Greece)

Results and Publications

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	03/02/2010		Yes	No