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Evaluation of Effectiveness of Mastic Gum in Functional Dyspepsia

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

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
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
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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 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