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Aromatic plant intervention for gastrointestinal tract symptoms

Submission date 22/03/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/03/2017	**Overall study status** Completed	
Last Edited 25/09/2017	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Digestive problems are among the most frequent reasons for patients to visit primary health care. The most common symptoms include dyspepsia-like symptoms and irritable-bowel-syndrome-(IBS) like symptoms. Dyspepsia (indigestion) is pain or discomfort in the stomach and under the ribs. Irritable bowel syndrome (IBS) is a long-term condition that can cause stomach cramps, bloating, diarrhoea and/or constipation. Treatments derived from aromatic plants may reduce these symptoms. The aim of this study is to find out whether droplets derived from a specific combination of aromatic plants reduce dyspepsia-like and IBS-like symptoms.

Who can participate?
Patients aged over 18 with dyspepsia-like or IBS-like symptoms

What does the study involve?
Participants are divided into two groups according to the nature of their symptoms (dyspepsia-like symptoms or IBS-like symptoms). Within these groups participants are randomly allocated to receive either droplets derived from aromatic plants or placebo (dummy) droplets. Participants take the droplets by mouth once a day for four weeks. Dyspepsia-like symptoms or IBS-like symptoms are assessed at the start of the study and after four weeks.

What are the possible benefits and risks of participating?
There are no direct benefits or risks to participants. All ingredients of the droplets have been consumed for centuries in Crete.

Where is the study run from?
University of Crete (Greece)

When is the study starting and how long is it expected to run for?
March 2017 to September 2017

Who is funding the study?
University of Crete (Greece)

Who is the main contact?
Prof. Christos Lionis

Contact information

Type(s)
Scientific

Contact name
Prof Christos Lionis

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Contact details
Clinic of Social and Family Medicine,
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71003

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16251

Study information

Scientific Title
The use of aromatic plants in reducing the severity of functional gastro-intestinal tract symptoms: a randomised controlled trial

Acronym
APLI-GtS

Study objectives
This intervention may reduce the severity of dyspepsia-like and IBS-like symptoms in patients suffering from GI tract functional problems.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Bioethics Committee, 7th Health Region of Greece, No 14726/11-10-16, 03/11/2016, ref: 16251

Study design
Proof-of-concept two-arm placebo-controlled pre-/post-evaluation trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
GI-tract functional problems including dyspepsia-like and IBS-like symptoms

Interventions
Patients will be divided into two arms according to the nature of their symptoms (Arm A: dyspepsia-like symptoms, Arm B: IBS-like symptoms). The randomization is a block randomization with age group and gender strata. It is generated using R-statistics and blockrand command. Patients within the two arms of the study will be randomized into two groups:
1. The intervention group receive droplets derived from aromatic plants. The aromatic plants that will be used are Origanum vulgare subsp. Hirtum and/or Origanum onites, Salvia fruticosa and/or Salvia officinalis and Origanum dictamnus. The mixture will be resolved in virgin-olive oil in droplets of 0.5 mg each.
2. The control group receive a placebo droplet
The dosage given is 0.5 ml, once per day, droplet per os. The duration of the study will be four weeks.

Intervention Type
Supplement

Primary outcome measure
Severity of dyspepsia-like symptoms, assessed using the COLRAD questionnaire at baseline and after one month of administration

Secondary outcome measures
Severity of IBS-like symptoms, assessed using the IBS-SSS questionnaire at baseline and after one month of administration

Overall study start date
02/03/2017

Completion date
31/01/2018

Eligibility

Key inclusion criteria
1. Participant aged >18 years
2. Suffering from GI-tract discomfort such as dyspepsia-like and/or IBS-like symptoms
3. Patients not receiving any other medication for the GI-tract symptoms in the previous two weeks
4. Pregnant women
5. Patients with history of cancer

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
72 individuals (36 participants in each arm, with each arm comprised of two groups of 18 patients)

Key exclusion criteria
1. Participant does not have capacity to complete study questionnaire
2. Participant is under the age of 18
3. Participant currently receiving medication for his/her treatment or deny

Date of first enrolment
03/04/2017

Date of final enrolment
15/12/2017

Locations

Countries of recruitment
Greece

Study participating centre
University of Crete
Clinic of Social and Family Medicine

Faculty of Medicine
PO Box 2208
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Sponsor information

Organisation
University of Crete

Sponsor details
Clinic of Social and Family Medicine
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PO Box 2208
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Sponsor type
Research organisation

Website
http://www.fammed.uoc.gr/Joomla/

ROR
https://ror.org/00dr28g20

Funder(s)

Funder type
University/education

Funder Name
University of Crete

Alternative Name(s)
UoC

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Greece

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal is expected at the end of 2018.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Christos Lionis.

IPD sharing plan summary
Available on request