

Aromatic plant intervention for gastrointestinal tract symptoms

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

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

ORCID ID

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Contact details

Clinic of Social and Family Medicine,

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Heraklion

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71003

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

Heraklion

Greece

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Sponsor information**Organisation**

University of Crete

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

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