

Geraniol treatment of irritable bowel syndrome patients

Submission date 09/07/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/07/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/08/2023	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Irritable bowel syndrome (IBS) is a disease that can cause bloating, diarrhoea, constipation and intestinal discomfort. It can also lead to dysbiosis, which is where there is a disturbance or imbalance in the microbes that live in the gut (gut microbiota), along with inflammation of the intestines. There is not yet an effective way to treat IBS.

Essential oils, which are natural oils that come from plants, are considered to be antibacterial and anti-inflammatory, and are known to have an effect on gut microbiota. Geraniol is a compound that comes from essential oils from plants such as lemongrass and rose, and has been shown to have strong anti-inflammatory properties. Additionally, geraniol has been shown to be effective against colitis (a symptom of IBD) and dysbiosis in studies on mice.

As geraniol is safe for humans, we aimed to determine whether geraniol was effective at reducing inflammation and dysbiosis in patients with IBD.

Who can participate?

Patients with IBS aged 18-65, weighing between 48 and 104 kg with a BMI of less than 27.

What does the study involve?

Participants will be asked to take capsules of geraniol orally daily for 4 weeks (geraniol dose depends on body weight) and will be asked to provide fecal samples before treatment, after 4 weeks of treatment and 4 weeks after treatment has ended.

What are the possible benefits and risks of participating?

The possible benefit to participants of taking part is that previous studies have shown that similar treatments that affect gut microbiota lead to improvement of IBD symptoms such as bloating and diarrhoea; therefore, this may also be the case for geraniol treatment. There are no known risks to participants of taking part.

Where is the study run from?

1. Inflammatory Bowel Disease Unit, S. Orsola-Malpighi Hospital, Bologna, Italy (lead centre)
2. Spedali Civili di Brescia, Brescia, Italy (satellite centre)

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

January 2015 to December 2017

Who is funding the study?

1. University of Bologna (Italy)
2. Xeda International SA (France)

Who is the main contact?

Professor Enzo Spisni

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

IBS-22-05

Study information

Scientific Title

Effect of dietary geraniol on intestinal dysbiosis in irritable bowel syndrome patients

Acronym

IBS-Ge-OH

Study objectives

Geraniol could be a food supplement with anti-inflammatory and anti-dysbiotic activity in irritable bowel syndrome (IBS) patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the AOU Policlinico S. Orsola-Malpighi, 29/10/2013, CE code 100/2013/U/Sper

Ethics Committee of the ASST Spedali Civili di Brescia, 03/06/2015, CE code NP2047

Study design

Interventional open label non-randomised multi-centre pilot study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Irritable bowel syndrome (IBS)

Interventions

Participants underwent geraniol treatment for a period of 4 weeks and was taken daily at a maximum dose of 8 mg/Kg/day. Geraniol was provided in capsules containing 150 mg geraniol and 160 mg soy lecithin. The number of capsules given was calculated depending on the body weight of participants.

1. Participants weighing 48-59 kg were given a dose of 3 capsules per day
2. Participants weighing 60-74 kg were given a dose of 4 capsules per day
3. Participants weighing 75-89 kg were given a dose of 5 capsules per day
4. Participants weighing 90-104 kg were given a dose of 6 capsules per day.

After taking geraniol daily for 4 weeks, there was 4 weeks of follow up - a 'wash out' period where geraniol was not taken.

Participants were asked to provide fecal samples before treatment, after 4 weeks of treatment and 4 weeks after treatment was complete.

Intervention Type

Supplement

Primary outcome(s)

Changes in fecal microbiota composition after 4 weeks of geraniol administration was measured through phylogenetic DNA array analysis of fecal samples before starting geraniol treatment (visit 1), after 4 weeks of treatment (visit 2) and 4 weeks after treatment finished (visit 3, after 4 weeks of wash out).

Key secondary outcome(s)

1. Fecal microbial composition in patients with IBS was measured using phylogenetic DNA array analysis of fecal samples before starting geraniol treatment (visit 1).
2. Changes in the microbiota-immune system axis was measured through Luminex analysis of plasma for the levels of cytokines and chemokines involved in the T helper 17 pathway (IL-1 β , IL-4, IL-6, IL-10, IL-17A, IL-17F, IL-21, IL-22, IL-23, IL-25, IL-31, IL-33, IFN- γ , sCD40L, TNF- α). This was measured before starting geraniol treatment (visit 1), after 4 weeks of treatment (visit 2) and 4 weeks after treatment finished (visit 3).

Completion date

31/12/2017

Eligibility

Key inclusion criteria

- 1) Signature of informed consent
- 2) Irritable bowel syndrome, meeting the Roma III criteria for diagnosis of IBS
- 3) Body weight between 46 kg and 100 kg, with BMI less than 27
- 4) Aged 18-65 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Total final enrolment

19

Key exclusion criteria

1. Taken steroid anti-inflammatory drugs, antibiotics or supplements and/or functional foods containing probiotics or prebiotics in the months prior to enrolment
2. Pregnancy, suspected pregnancy or breastfeeding
3. Diagnosed with IBD
4. Coeliac disease
5. Severe systemic disease
6. Lactose intolerant
7. Known food allergies
8. Known or suspected hypersensitivity to geraniol or soy
9. Serious concomitant diseases that contraindicate participation in the study (in the opinion of the investigator)
10. Use of experimental drugs in the 2 months prior to enrolment

Date of first enrolment

01/03/2015

Date of final enrolment

30/10/2017

Locations

Countries of recruitment

Italy

Study participating centre

IBD Unit

S. Orsola Hospital, Pad. 5, Via Massarenti 49

Bologna

Italy

40126

Study participating centre

Gastroenterology Unit

Spedali Civili di Brescia, Piazzale Spedali Civili, 1

Brescia

Italy

25123

Sponsor information

Organisation

University of Bologna

ROR

<https://ror.org/01111rn36>

Organisation

Xeda international

Funder(s)

Funder type

Not defined

Funder Name

Università di Bologna

Alternative Name(s)

University of Bologna, UNIBO

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Italy

Results and Publications

Individual participant data (IPD) sharing plan

Data was collected in pseudonymous form and explicit consent to provide raw data to third parties not involved in the clinical trial was not given by the patients. The explicit consent was given only to publish data in an aggregate form.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/12/2018	07/11/2019	Yes	No
Results article		10/10/2022	23/08/2023	Yes	No
Participant information sheet			02/04/2019	No	Yes