ISRCTN47041881 https://doi.org/10.1186/ISRCTN47041881

Geraniol treatment of irritable bowel syndrome patients

Submission date
09/07/2018

Recruitment status
No longer recruiting

Registration date
19/07/2018

Overall study status
Completed

Last Edited
23/08/2023

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

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 partcipants.
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 measure
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).

Secondary outcome measures
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-1β, 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).

Overall study start date
01/01/2015

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
25

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

Sponsor details

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40126

Sponsor type
University/education

Website
http://www.unibo.it/en/homepage

ROR
https://ror.org/01111rn36

Organisation
Xeda international

Sponsor details
Route nationale 7 - ZAC LA CRAU -
SAINT ANDIOL
France
13670

Sponsor type
Industry

Website
https://www.xeda.com/

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

Publication and dissemination plan
We intend to publish in BMC Complementary and Alternative Medicine.

Intention to publish date
01/09/2018

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?
Participant information sheet			02/04/2019	No	Yes
Results article	results	19/12/2018	07/11/2019	Yes	No
Results article		10/10/2022	23/08/2023	Yes	No