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Role of AHT#1 food supplement in symptom control of IBS-D

Submission date
08/06/2018

Recruitment status
No longer recruiting

Registration date
20/02/2019

Overall study status
Completed

Last Edited
24/04/2019

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
IBS is a common bowel complaint and so far there is no single long-lasting cure for the symptoms such as bloating and diarrhoea. IBS does not lead to death, but it is important due to the effect that these symptoms have on quality of life (QoL), NHS costs and days off work. This study aims to test whether the food supplement AHT#1 helps people with IBS symptoms. The supplement contains curcumin, vitamin D3 and green tea. Previous studies suggest that these supplements individually can be effective in IBS and also inflammatory bowel disease, so therefore this study is testing the benefit of a combination supplement in IBS symptoms.

Who can participate?
Adults with IBS-D (IBS that involves diarrhoea rather than constipation).

What does the study involve?
Participants will take 2 capsules of AHT#1 a day for 28 days and complete the bowel symptom diary. The patient will have a follow-up clinic appointment at 28 days for review and to check the supplement pack to see how many capsules are left and to return the bowel diary. The patient may choose to take the product for 56 more days and will be given the supply in clinic. They return 2 months later to clinic and complete the final IBS-SSS questionnaire prior to the appointment. The supplement pack will be checked for to see how many capsules are left. If the supplement appears to be helping with IBS symptoms, the participant can request 3 month's supply of free product.

What are the possible benefits and risks of participating?
There is a very low risk of problems from taking the AHT#1 food supplement. Turmeric and caffeine may stimulate a bowel movement in some people. If there is any worsening of IBS symptoms, the patient should stop taking the food supplement. Research has shown that taking turmeric, vitamin D and green tea extract separately can reduce IBS symptoms. This means that it is possible that some participants will experience an improvement in the number of bowel movements, stool consistency, bloating and associated pain after taking the capsules.

Where is the study run from?
University College London

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

Who is funding the study?
ProfBiotics Ltd

Who is the main contact?
Dr Valentina Passananti

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
18/0106

Study information

Scientific Title
Role of AHT#1 (curcumin/green tea/vitamin D) food supplement on symptom control in diarrhoea-predominant irritable bowel syndrome (IBS-D) as assessed by the IBS Severity Scoring System (IBS-SSS)

Study objectives
IBS is a common bowel complaint and so far there is no single long lasting cure for the symptoms such as bloating and diarrhoea. IBS has no attributable mortality, but it is important due to the effect that symptoms have on quality of life (QoL) and as consequence a big cost for the public service.The research will be undertaken to test whether the food supplement AHT#1, helps people with IBS and bloating. The supplement contains curcumin, vitamin D3 and green tea.Published evidence suggest that these supplements individually can be effective in IBS and also inflammatory bowel disease we would like investigate if the combination of supplement works better to reduce the severity of symptoms.
disease, so therefore this study is assessing benefit of combination supplement in IBS symptom severity score.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Application for ethics approval to be submitted in June 2018

Primary study design
Interventional

Study design
Non-randomised study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
IBS with diarrhoea as the predominant symptom (IBS-D)

Interventions
Individuals who suffer with IBS-D (diarrhea-predominant IBS) will be identified by looking at the last clinic letter and seeing if they match the eligibility criteria. If they are eligible they will be posted a cover letter and patient information sheet about the trial at least a week before they are due in clinic. At the end of their routine clinical visit they express interest in participating or to receive further information about the study, then a member of the research team will speak to them about the study in more detail and obtain informed consent if the participant is still willing to proceed. After written consent the patient will be enrolled onto the study. The IBS symptom severity score (IBS-SSS) questionnaire should be completed the day before the patient starts taking the capsules, this is day 0. The patient takes 2 capsules of AHT#1 a day for 28 days and they will complete a bowel diary. One AHT#1 capsule contains: 250 mg curcumin from Omniactive Technologies, 12.5 µg Vitamin D3 and 100 mg of caffeine-free (very low caffeine) green tea extract. The patient will have a follow-up clinic appointment at 28 days for review and to check the supplement pack regarding compliance (number of capsules left) and to return the bowel diary.
The patient may choose to take the product for 56 more days and will be given the supply in clinic. They return 2 months later to the clinic and will complete the final IBS-SSS questionnaire prior to the appointment. The supplement pack will be checked for compliance. Should the patient still be gaining benefit, they can request 3 months' supply of free product.

Intervention Type
Supplement

Primary outcome(s)
Change in IBS symptom severity score (IBS-SSS) assessed by questionnaire on day 0 and day 28

Key secondary outcome(s)
1. Bowel movement frequency assessed using the bowel diary over 28 days
2. Stool consistency assessed using the bowel diary over 28 days
3. Number of days without abdominal pain assessed using the bowel diary over 28 days

Completion date
30/04/2019

Eligibility

Key inclusion criteria
1. Diagnosis of diarrhoea-predominant IBS (as per Rome IV criteria)
2. Aged 18-99 years
3. No major co-morbidity
4. IBS-SSS score of >150
5. No evidence of inflammatory bowel disease/microscopic colitis or abdominal surgery (other than appendicectomy)
6. Able to give informed consent.
7. Be able to quantify previous treatments
8. Confirmed stable diet for duration of the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Key exclusion criteria
1. Prior abdominal surgery other than appendectomy and cholecystectomy. The investigator will clinically
exclude bile salt malabsorption.
2. Participating in another trial
3. Pregnant or breast feeding
4. Unwilling to maintain stable doses of IBS therapy (anti-muscarinics, anti-diarrhoeals, anti-depressants)
5. Unwilling to maintain stable diet for the duration of the trial
6. Being in the opinion of the investigator unsuitable
7. Insufficient knowledge of English to complete the questionnaire/diary
8. Hypersensitivity to any component of the supplement
9. Drug interactions with any component of the supplement

Date of first enrolment
01/08/2018

Date of final enrolment
01/01/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College of London Hospital
235 Euston Road
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
University College of London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
ProfBiotics Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	version v1.0				

Participant information sheet	10/02/2018	01/04/2019	No	Yes