The effect of CanChew®, cannabidiol (CBD) containing chewing gum on Irritable Bowel Syndrome

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Investigate the effect of administration of CBD by means of CanChew® chewing gum versus a placebo on pain, IBS symptoms and perceived wellbeing in patients with IBS.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON43003

Source
ToetsingOnline

Brief title
The CANdidate study

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
irritable bowel syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,Axim Biotechnologies

Intervention

Keyword: Cannabidiol, IBS, Intestine

Outcome measures

Primary outcome

Investigate the effect of administration of CBD by means of CanChew® chewing gum versus a placebo on pain, IBS symptoms and perceived wellbeing in patients with IBS.

Secondary outcome

n.a.

Study description

Background summary

IBS is the most common functional gastrointestinal disorder with a prevalence worldwide ranging from 9-23%. Complaints include abdominal discomfort or pain, and altered bowel habits. Although the condition is not life-threatening, it strongly impairs quality of life and up to now there is no cure. It is thought that symptoms are caused by altered gut motility and secretion, visceral hypersensitivity, and disturbances of brain-gut interactions. manipulation of the CB1 and CB2 receptors by (endo)cannabinoids (endocannabinoids are cannabinoids which are synthesized by the body itself) can alter gut motility and gut secretions. Besides that, evidence suggests that cannabinoids can decrease intestinal hypersensitivity as well. Therefore cannabidiol (CBD), is of special interest as it does not show psychoactivity, while still having therapeutic potential. Therefore we want to investigate if administration of CBD by means of CanChew® chewing gum versus a placebo has an effect on pain, IBS symptoms and perceived wellbeing in patients with IBS.

Study objective

Investigate the effect of administration of CBD by means of CanChew® chewing gum versus a placebo on pain, IBS symptoms and perceived wellbeing in patients with IBS.

Study design

A randomized, double-blind, cross-over trial of 8 weeks in total.

Intervention

Patients will, in this cross-over study, receive a maximum 6 chewing gums per day, either containing cannabidiol, or a placebo chewing gum. Both intervention periods will be 3 weeks with one week wash-out in between. Participants can take the chewing gum when in pain, they will give this pain a score and after 30 minutes of chewing they will give another score for the pain to see what effect the chewing gum has on pain.
The participants will keep a diary for 8 weeks in total to monitor the pain scores and changes in stools. Next to that they will fill in the IBS-QOL questionnaire after week 1, week 5 and week 8.

Study burden and risks

CBD does not show psycho-activity, is generally considered non-toxic, and does not induce changes in food intake, physiological parameters, and psychomotor functions. However, there are indications that CBD may inhibit certain cytochrome P450 enzymes, in particular CYP2C19 and CYP3A4. For this reason patients will be excluded when they use medicatie that involves the same enzymes. This will be evaluated by the principal investigator / gastroenterologist. There have been no reports of clinical interactions with medication in the literature as far as we know and chronic use of up to 1500mg/day are well tolerated in humans. Therefore no adverse effects are expected and risks are null.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Male
* Female, only when using the contraceptive pill
* Adults, aged 18-65
* IBS, diagnosed according to the Rome III criteria
* More than 3 moments of pain a week with a VAS-score of 4 and higher
* Signed informed consent

Exclusion criteria

* Use of SSRIs, tramadol or tramagetic
* History of intestinal surgery that might interfere with the outcome of the study
* Female patients: currently pregnant, breast-feeding or intending to become pregnant during the study, judged by the persons self
* Female who is not using the contraceptive pill.
* Are an employee of the department of Human Nutrition at Wageningen UR, or employee of Ziekenhuis Gelderse Vallei
* Participate in another research study
* Alcohol use (male more than 14 servings a week, female more than 7 servings a week)
* Hypersensitivity to one of the ingredients of the chewing gum
* Cannabis use is from 3 months before untill the end of the study not allowed
* Drug use (CYP2C19 and CYP3A4) metabolised; medication will be evaluated for this by the principal and medical investigator.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-03-2017
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	06-12-2016
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL58588.081.16