ISRCTN49036618 https://doi.org/10.1186/ISRCTN49036618

Effects of Kivia powder on gut health in patients with occasional constipation

Submission date
26/01/2012

Recruitment status
No longer recruiting

Registration date
23/02/2012

Overall study status
Completed

Last Edited
05/09/2014

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The kiwifruit is of traditional interest in digestive health. In this study, a freeze-dried extract of kiwifruit containing zyactinase was evaluated for its safety and effectiveness for aiding with constipation in individuals with occasional constipation.

Who can participate?
Individuals aged 18-65 with occasional constipation.

What does the study involve?
Participants received one of the following two treatments: one sachet of Kivia powder, containing the active ingredient zyactinase, daily for 4 weeks, or an identical placebo (dummy) powder. We measured the effectiveness of zyactinase compared to placebo in terms of bowel movement frequency (number of bowel movements per week), gut health, including stool form, bowel urgency, abdominal bloating, abdominal discomfort or pain, satisfaction with bowel habits, flatulence, burping, the use of rescue medication, and safety based on adverse events.

What are the possible benefits and risks of participating?
The possible benefits are improvement of gut health while alleviating occasional constipation.

Where is the study run from?
The study was conducted at the Staywell Research clinical research site located in Northridge, CA, USA.

When is the study starting and how long is it expected to run for?
The study ran from August 2010 to October 2011.

Who is funding the study?
Vital Foods Processors Ltd, Auckland, New Zealand.

Who is the main contact?
Jay Udani, MD
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Contact information

Type(s)
Scientific

Contact name
Dr Jay Udani

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Additional identifiers

Protocol serial number
VTLF1400

Study information

Scientific Title
Effects of Kivia powder on gut health in patients with occasional constipation: a randomized double-blind, placebo-controlled study

Study objectives
The aim of the study is to evaluate the ability and safety of a proprietary extract of kiwifruit containing zyactinase in individuals with occasional constipation by observing change in bowel movement frequency.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board (IRB) (Copernicus Group IRB, Cary, NC); August 2010

Primary study design
Interventional

Study design
Randomized double-blind placebo-controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Constipation

Interventions

Subjects received one of the following two interventions: identical placebo or one sachet of Kivia powder, containing the active ingredient zyactinase (5,500 mg), daily for four weeks.

Eighty-seven men and women were randomized to the study (43 to Kivia powder and 44 to placebo), and 82 completed the study (n=39 in the treatment group). These 82 subjects were included in the analysis. Five subjects did not complete the study because they were lost to follow-up.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Kivia powder

Primary outcome(s)
Efficacy of Kivia powder compared to placebo on bowel movement frequency (the number of bowel movements per week)

Key secondary outcome(s)
Efficacy of Kivia powder compared to placebo:
1. On gut health, including stool form (Bristol Stool Scale)
2. Bowel urgency
3. Abdominal bloating
4. Abdominal discomfort or pain
5. Satisfaction with bowel habits, flatulence and burping
6. The use of rescue medication and safety, based on adverse events

Measured in daily diaries which were collected on each visit such that V1 (Screen/Run-in), V2 (Randomization) = Day 0, V3= Week 2, V4 (End of Study) = Week 4

Completion date
31/10/2011

Eligibility

Key inclusion criteria
1. Healthy adults between 18 and 65 years of age and with a body mass index (BMI) between 20 and 35 kg/m2
2. The subjects had symptoms consistent with occasional constipation; these included at least two of the following occurring during the two-week run-in period:
2.1. Three or fewer defecations per week
2.2. Straining during at least 25% of defecations
2.3. Lumpy or hard stools in at least 25% of defecations
2.4. A sensation of incomplete evacuation for at least 25% of defecations
2.5. A sensation of anorectal obstruction or blockage for at least 25% of defecations
2.6. Manual maneuvers to facilitate at least 25% of defecations (e.g., digital evacuation, support of the pelvic floor)
3. Subjects were also required to be willing to maintain his or her habitual food and beverage

intake (other than substitution of study food for similar products) and physical activity patterns throughout the study period. The subjects were judged by the investigator to be in general good health on the basis of their medical histories
4. Informed consents were signed

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Any significant gastrointestinal condition that would potentially interfere with the evaluation of the study product, including, but not limited to, inflammatory bowel disease (ulcerative colitis or Crohns)
2. A history of frequent diarrhea
3. A history of surgery for weight loss (including gastric bypass or lapband)
4. A history of perforation of the stomach or intestines
5. Gastroparesis, or clinically important lactose intolerance
6. Clinically significant renal, hepatic, endocrine (including diabetes mellitus), cardiac, pulmonary, pancreatic, neurologic, hematologic, or biliary disorders
7. Known allergy or sensitivity to kiwifruit
8. A recent (within two weeks of visit 1, week -1) episode of acute gastrointestinal illness such as nausea, vomiting, or diarrhea
9. A history or presence of cancer in the prior two years, except for nonmelanoma skin cancer
10. A recent history of (within 12 months) or a strong potential for alcohol or substance abuse
11. Participation in a clinical study with exposure to any nonregistered drug product within 30 days prior to the study 12. Any condition believed to interfere with ability to provide informed consent or comply with the study protocol, or believed to confound the interpretation of the study results or put the person at undue risk
13. Any active infection or any infection in the previous month requiring antibiotics, antiviral medication, or hospitalization
14. Diabetes requiring medication
15. Untreated or unstable hypothyroidism
16. Weight loss or gain of ≥ 20 pounds in the previous three months
17. A clinically significant abnormal physical examination
18. An active eating disorder, including anorexia nervosa, bulimia, and/or obsessive compulsive eating disorders
19. Central neurological disorders, including, but not limited to, spinal cord injuries, multiple sclerosis, and Parkinsons disease

20. An unwillingness to discontinue all laxatives or all dietary supplements
21. Pregnancy, lactation, or an unwillingness to use adequate contraception for the duration of the study

Date of first enrolment
01/08/2010

Date of final enrolment
31/10/2011

Locations

Countries of recruitment
United States of America

Study participating centre
18250 Roscoe Blvd, Suite 220
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91325

Sponsor information

Organisation
Vital Food Processors Ltd (New Zealand)

Funder(s)

Funder type
Industry

Funder Name
Medicus Research, LLC (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/06/2013		Yes	No