ISRCTN78436478 https://doi.org/10.1186/ISRCTN78436478

Effect of a fermented blueberry-alfalfa drink on tolerability and blood parameters of healthy volunteers

Submission date
15/07/2022

Recruitment status
No longer recruiting

Registration date
30/09/2022

Overall study status
Completed

Last Edited
08/01/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims
A growing awareness of increasingly widespread lifestyle diseases has led consumers to pay more attention to their eating habits. Human eating habits and lifestyles have changed significantly in recent decades, and the resulting public health problems are increasing the demand for functional and health-promoting products. Of these, various products based on plant raw materials (e.g. cereals and legumes) have found the most popularity as the components they contain have a potentially beneficial effect on human health. Various phytochemicals with antioxidant properties in plant raw materials provide protection against cardiovascular (heart) and other chronic diseases caused by elevated oxidative stress. Phytochemicals are bioactive non-nutrient compounds of plant origin. The most studied compounds include polyphenols, flavonoids, tannins, saponins and triterpenoids. The antioxidant properties of the above-mentioned compounds, which are important in balancing the oxidative processes in the human body due to chronic diseases, have been studied the most. Alfalfa (Medicago sativa) has been used in folk medicine for a long time. Alfalfa aqueous extract is an excellent natural source of minerals, containing many minerals such as calcium, magnesium, iron, zinc and vitamin B6. In addition to minerals and vitamins, alfalfa also contains carotenes, isoflavonoids, alkaloids, saponins, phytoestrogens, L-channelavanine and various other compounds. Positive effects of alfalfa aqueous extract on serum cholesterol fractions and liver enzymes have been reported in several animal studies. Blueberry (Vaccinium myrtillus) was one of the first foods to receive the title of "superfood". In the case of blueberries, its anthocyanin content is considered to be particularly important and is attributed a number of beneficial effects. The beneficial effects of blueberries on reducing the risks of modern lifestyle diseases (such as cardiovascular disease, type 2 diabetes, etc) have been most studied and described. The aim of this study is to evaluate the impact of a fermented blueberry-alfalfa drink on the well-being and health parameters of relatively healthy volunteers.

Who can participate?
Generally healthy people, from age 18 years

What does the study involve?
Participants are asked to consume 30 ml of a fermented blueberry-alfalfa drink daily for a period of 21 days. Participants are asked to assess their well-being and gastrointestinal (digestive) effects daily, and to provide blood samples to evaluate the safety parameters.

What are the possible benefits and risks of participating?
Participants receive an assessment of their health status and if necessary, recommendations for future steps. The study causes minimal inconvenience to participants as blood samples are taken by an experienced nurse, and the procedure is safe. However, as with any blood test, there may be bruising and discomfort at the site of the blood test. The amounts of blood will be small enough not to cause fatigue or anaemia.

Where is the study run from?
BioCC OÜ (Estonia)

When is the study starting and how long is it expected to run for?
July 2021 to December 2021

Who is funding the study?
Estonian Research Council (Estonia)

Who is the main contact?
Merle Ratsep, merle.ratsep@biocc.ee

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
SHOT1

Study information

Scientific Title
Impact of a fermented blueberry-alfalfa drink on safety and tolerability and on blood parameters of healthy volunteers

Acronym
SHOT

Study objectives
The consumption of fermented blueberry-alfalfa drink is well tolerated and has no side effects on safety parameters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/09/2021, Research Ethics Committee of the University of Tartu (UT REC, Raekoja plats 9, 51004, Tartu, Estonia; +372 (0)737 6215; eetikakomitee@ut.ee), ref: 350/T-15

Primary study design
Interventional

Study design
Interventional non-randomized study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Effect of fermented blueberry-alfalfa drink on tolerability and blood parameters of healthy volunteers

Interventions
All participants drink the 30 ml fermented blueberry-alfalfa drink daily for 21 days.

Intervention Type
Supplement

Primary outcome(s)
Adverse events measured using a patient diary (follow chart), a self-administered follow-up questionnaire filled out once per day for 21 days

Key secondary outcome(s)
1. Safety parameters (e.g. white blood [WBC] and red blood [RBC] indices, inflammation [CRP], kidney and liver parameters) measured by standard laboratory methods in the United Laboratories of the Tartu University Hospital at baseline and the end of the study
2. Experimental parameters (e.g. adiponectin and leptin) measured from the blood samples using ELISA commercial kits (R&D Systems) and blood samples taken at baseline and the end of the study

Completion date
30/12/2021

Eligibility

Key inclusion criteria
1. Written informed consent
2. Aged 18 years and over
3. Willingness to maintain a stable diet and physical activity level
4. Willingness to cease using probiotic products and supplements (except vitamin D) during the study period
5. Normal or not clinically relevant deviations in safety laboratory values

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
15

Key exclusion criteria
1. Acute or chronic inflammatory disease
2. Gastrointestinal diseases (e.g. Crohn's disease, inflammatory bowel disease, ulcerative colitis)

Date of first enrolment
27/09/2021

Date of final enrolment
04/10/2021

Locations

Countries of recruitment
Estonia

Study participating centre
BioCC OÜ
Riia 181A
Tartu
Estonia
50410

Sponsor information

Organisation
BioCC OÜ

Funder(s)

Funder type
Research council

Funder Name
Eesti Teadusagentuur

Alternative Name(s)
Estonian Research Council, Estonian Research Council (ETAG), ETAG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Estonia

Results and Publications

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

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