ISRCTN33471815 https://doi.org/10.1186/ISRCTN33471815

Blood pressure lowering effect of Fruitflow® (tomato extract)

Submission date
28/04/2016

Recruitment status
No longer recruiting

Registration date
29/04/2016

Overall study status
Completed

Last Edited
24/01/2019

Condition category
Other

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

Plain English summary of protocol

Background and study aims
In recent years, there has been considerable interest in the use of natural food components as functional foods to treat high blood pressure (hypertension), especially for people with borderline to mild high blood pressure that does not warrant the prescription of anti-hypertensive drugs. Over the last 15 years we have studied a tomato extract that is now marketed as Fruitflow. We do not know how much Fruitflow should be consumed in order to have a reasonable blood pressure lowering effect in moderately hypertensive people. We therefore want to examine the effects of consuming Fruitflow on blood pressure in a small group of healthy people.

Who can participate?
Healthy male volunteers, over 35 years of age, with no history of cardiovascular (heart) disorders but with some elevated risk factors and resting blood pressure above 135/90

What does the study involve?
Participants are randomly allocated to consume either one of two doses of Fruitflow or a placebo (dummy) supplement. Their blood pressure is then assessed every hour for 24 hours. Blood samples are also taken. Each participant undergoes all three interventions.

What are the possible benefits and risks of participating?
Participants will receive insights into their 24-hour blood pressure patterns, and will be compensated for loss of time. There are no other direct benefits. The risks involved with participation relate to the risks associated with blood sampling, which are minimised by strict adherence to standard protocols. The supplement is a food product which can be obtained in several forms in supermarkets or over the counter in pharmacies. No specific risks are associated with this supplement.

Where is the study run from?
University of Oslo (Norway)

When is the study starting and how long is it expected to run for?
March to June 2016

Who is funding the study?
Provexis (UK)

Who is the main contact?
Prof Asim Duttaroy
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
690391

Study information

Scientific Title
Blood pressure lowering effect of Fruitflow® (tomato extract)

Study objectives
We will examine the effects of consuming Fruitflow® (150 mg and 300 mg) on blood pressure after 24h in a small group of healthy subjects (n=12).

In order to test the physiological relevance of the observed effects of Fruitflow® on ACE, some initial work is required to set basic parameters. This work divides into two main phases. The first is to allow some estimate of likely dosage ranges. This information would be useful to indicate whether the primary use of this agent for lowering ACE activity is likely to be medicinal or whether it can be used as a functional food ingredient.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regionale Komiter for Medisinsk og Helsefaglig Forskningsetikk (REK), ref no: 2015/396/REK sør-øst C

Study design
Randomised cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
School

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Not Applicable

Interventions
For the initial pilot tests, 12 subjects will be selected to form a homogenous investigation group. A crossover design will be employed. Two intervention doses will be tested (150 mg and 300 mg Fruitflow) and compared to placebo. Thus each subject will undergo three interventions. In addition, subjects will undergo a screening procedure in advance of the interventions in which ambulatory blood pressure will be assessed.

Intervention Type
Supplement

Primary outcome measure
Ambulatory blood pressure monitoring over a 24-hour period will be used as the main outcome measure. Protocol to be confirmed. Static blood pressure measurements may also be carried out at convenient intervals. The primary end point is change in mean systolic blood pressure (mmHg) between baseline and each follow up point.

Secondary outcome measures
1. Change in mean diastolic blood pressure between baseline and each follow up point
2. Plasma ACE assessed at to and at t3 hours after consumption of supplements
3. Platelet response assessed at to and at t3 hours after consumption of supplements

Overall study start date
01/03/2016

Completion date
10/06/2016

Eligibility

Key inclusion criteria
1. Male subjects
2. No history of cardiovascular disorders but with some elevated risk factors
3. Over 35 years of age
4. Resting blood pressure above 135/90
5. Normal blood level ACE activity
6. Normal platelet aggregation response against ADP
7. Should not take any blood pressure medications and platelet-modulating drugs for at least 2 weeks

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Male

Target number of participants
15

Key exclusion criteria
Does not fulfill inclusion criteria

Date of first enrolment
05/03/2016

Date of final enrolment
10/06/2016

Locations

Countries of recruitment
Norway

Study participating centre
University of Oslo
Dept of Nutrition
IMB
Faculty of Medicine
Oslo
Norway
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Sponsor information

Organisation
Provexis (UK)

Sponsor details
58 Queens Road
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United Kingdom
RG1 4RP

Sponsor type
Industry

Website
http://provexis.org

Organisation
Inven2 (Norway)

Sponsor details
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Sponsor type
Industry

Website
http://www.inven2.com/no

Organisation
Provexis (United Kingdom)

Sponsor details

Sponsor type
Not defined

Website
http://www.provexis.org/

ROR
https://ror.org/046pkq184

Funder(s)

Funder type
Industry

Funder Name
Provexis (UK)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

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?
Results article	results	01/06/2018	24/01/2019	Yes	No