

# Blood pressure lowering effect of Fruitflow® (tomato extract)

<b>Submission date</b> 28/04/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/04/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/01/2019	<b>Condition category</b> Other	<input type="checkbox"/> 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

**Protocol serial number**  
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

## **Study type(s)**

Other

## **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(s)**

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.

## **Key secondary outcome(s)**

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

## **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Male

**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)

## Organisation

Inven2 (Norway)

## Organisation

Provexis (United Kingdom)

## ROR

<https://ror.org/046pkq184>

## Funder(s)

### Funder type

Industry

### Funder Name

Provexis (UK)

## Results and Publications

### 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?
<a href="#">Results article</a>	results	01/06/2018	24/01/2019	Yes	No