

Investigating whether different doses of Fruitflow have equal impact on blood platelets in different healthy subjects

Submission date 16/02/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/02/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 31/10/2022	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

For many years there has been an interest in the possible benefit to public health from the use of natural food components in preventing chronic illnesses such as cardiovascular diseases. One such natural food ingredient which has been much studied is a tomato extract now marketed as Fruitflow. Fruitflow is a natural antiplatelet (preventing blood clots from forming).

This study plans to investigate whether, due to differences in platelets in the normal population, different doses of Fruitflow may lead to similar responses, in different individuals. This would help to determine whether personalised doses of Fruitflow should be recommended. The study will test how effective each dose of Fruitflow is, and whether it would be possible and appropriate to carry out a larger trial with more participants at a later stage.

Who can participate?

Healthy male subjects aged over 30 years, without a history of cardiovascular disease, and who are not currently taking supplements or medications known to affect platelet function.

What does the study involve?

The study will involve a screening visit, in which suitability for inclusion is assessed, followed by a total of five trips to the University of Oslo Faculty of Medicine. At each of these visits, a blood sample will be taken, after which, one of five different doses of the Fruitflow supplement will be consumed. Neither the subject nor the study investigators will know the dosage administered at each visit. Breakfast will be offered after the supplement and then the next morning, 24 h after taking the supplement, a second blood sample will be taken. Subjects will then have a break of 10 to 14 days before the next visit. This will be repeated for the five different doses of Fruitflow so that the effects of different doses on each individual participant can be examined.

What are the possible benefits and risks of participating?

There will be no direct benefits to participants, but they will be compensated for travel costs and loss of time.

No specific risks are associated with the supplement. The risks involved in participation relate to the risks associated with blood sampling, which will be minimised by strict adherence to standard protocols. The supplement is a food ingredient that is currently consumed in many countries worldwide and can be obtained in supermarkets, health food shops, and pharmacies.

Where is the study run from?

The Medical Faculty of the University of Oslo (Norway)

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

From December 2018 to June 2019

Who is funding the study?

DSM Nutrition Ltd (Switzerland)

Who is the main contact?

Professor Asim Duttaroy, a.k.duttaroy@medisin.uio.no

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Study information

Scientific Title

Evaluation of the equivalence of different doses of Fruitflow® in affecting blood platelet aggregation and thrombin generation capacity in a pilot study in healthy subjects

Study objectives

Due to the inherent heterogeneity in platelet response between individuals, different doses of a tomato extract known as Fruitflow (0, 30, 75, and 300 mg) may be equivalent to the standard daily dose of 150mg within individuals.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 19/12/2017, Regionale Komiteer for Medisinsk og Helsefaglig Forskningsetikk (REK) sør-Øst (Gullhaugveien 1-3, 0484 Oslo, Norway; +47 22845515; post@helseforskning.etikkom.no), ref: 20157396/REK/Sør-Øst

Study design

Double-blinded randomized cross-over pilot study with 5 masked interventions

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Reduction of platelet hyperactivity in healthy subjects

Interventions

The study sets out to examine whether 5 different doses of Fruitflow (0, 30, 75, and 300 mg) are equivalent to the standard daily dose of 150mg. The study will follow a double-blind randomised crossover design, in which five masked interventions will be administered to each subject, with interventions separated by a minimum of 10 days.

Intervention Type

Supplement

Primary outcome measure

Platelet aggregation in response to optimised adenosine diphosphate (ADP) agonist concentration, measured using light transmission aggregometry at baseline and 24 h

Secondary outcome measures

Thrombin generation capacity measured by fluorogenic substrate generation at baseline and 24 h

Overall study start date

01/01/2018

Completion date

30/06/2020

Eligibility

Key inclusion criteria

1. Male subjects
2. No history of cardiovascular disease
3. Aged ≥ 30 years
4. Normal haemostatic measurements
5. Normal platelet aggregation response to adenosine diphosphate (ADP) agonist
6. Not taking any supplements or medications known to affect platelet function, without a suitable washout period

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Male

Target number of participants

10-12

Total final enrolment

10

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/05/2018

Date of final enrolment

31/12/2018

Locations

Countries of recruitment

Norway

Study participating centre

University of Oslo

Dept of Nutrition

IMB Faculty of Medicine

Oslo

Norway

O316

Sponsor information

Organisation

DSM (Switzerland)

Sponsor details

DSM Nutritional Products Ltd

Wurmisweg 576

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CH-4303

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a.k.duttoroy@uio.medisin.no

Sponsor type

Industry

Website

<https://www.dsm.com/corporate/about/businesses/dsm-nutritional-products.html>

ROR

<https://ror.org/01fgq8278>

Funder(s)

Funder type

Industry

Funder Name

DSM Research

Alternative Name(s)

DSM Research BV

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Netherlands

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. Study data analysis will complete during 2020 and thus publication is planned for between late 2020 and early 2021.

Intention to publish date

30/06/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to commercial confidentiality.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/12/2021	31/10/2022	Yes	No