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

Submission date	Recruitment status	[_] Prospectively registered
16/02/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/02/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/10/2022	Circulatory System	

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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
FF pilot 01

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

Study type(s)
Treatment

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

Key secondary outcome(s))
Thrombin generation capacity measured by fluorogenic substrate generation at baseline and 24 h

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

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)

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

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