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Mulberry extract to modulate blood glucose in healthy adults

Submission date	Recruitment status	[_] Prospectively registered
11/11/2014	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/04/2015	Completed	[X] Results
Last Edited	**Condition category**	[X] Individual participant data
17/05/2023	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Reducing the health impact of dietary sugar intake is a public health priority. Mulberry leaf extract may reduce blood glucose responses following dietary sugar intake by reducing absorption of carbohydrates in the gut. Mulberry leaf extracts are widely consumed in Asia. This study will test a water-extracted mulberry-leaf food supplement (currently available over the counter) in adults with normal (non-diabetic) blood sugar levels. The study will test the effect of a single administration of three doses of mulberry leaf extract capsules and a placebo (dummy) capsule when taken at the same time as a standard sugary drink.

Who can participate?
32 healthy adults aged 18-65 with a BMI of 20-30.

What does the study involve?
Participants will be recruited to attend for four visits, at least 48 hours apart, in order to test each of the mulberry and placebo capsules. The capsules will all have an identical appearance. Neither participants nor the study team will be aware of the order that the supplements are given until all of the tests have been completed. Blood glucose and insulin levels will be measured at time-points over 2 hours.

What are the possible benefits and risks of participating?
Mulberry extract has an excellent safety profile, is widely consumed in Asia and is available over the counter in England. As far as we are aware, mulberry extract does not have any reported adverse reactions other than mild stomach symptoms such as wind and bloating. Participants will have a cannula/drip sited (small plastic tube in a vein) and there will be a risk of bruising and a small risk of inflammation/infection at the site. Local infection control/procedures will be followed when inserting the cannula.

Where is the study run from?
The Southampton Wellcome Trust Clinical Research Facility (UK).

When is the study starting and how long is it expected to run for?
The study will commence in the first quarter of 2015 and we aim to run the study over 3-6 months until we have completed four visits for 32 participants.

Who is funding the study?
The study is being funded by the Technology Strategy Board as part of a nutrition for life Programme led by Phynova.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MULBERRY 1.1

Study information

Scientific Title
Mulberry extract to modULate Blood glucosE Responses in noRmoglYcaemic adults (MULBERRY): a pilot study

Acronym
MULBERRY

Study objectives

An appropriate dose of mulberry extract co-administered with oral maltodextrin will reduce the incremental area under the curve for plasma glucose concentration over 120 minutes in normoglycaemic adults in a dose-dependent manner when compared to co-administration with placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration - submission pending

Study design
Single-centre double-blind randomised four-arm single-dose cross-over design to determine the efficacy, dose-response relationship and gastrointestinal side effects with respect to placebo

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Carbohydrate absorption

Interventions
The study will evaluate single doses (500 mg, 250 mg and 125 mg) of mulberry extract given at least 48 hours apart against placebo:

1. 500 mg mulberry extract (IminiNorm capsule) (equivalent to 25 mg deoxynojirimycin [DNJ])
2. 250 mg IminoNorm capsule (containing 12.5 mg DNJ)
3. 125 mg IminoNorm capsule (containing 6.75 mg DNJ)
4. Matched placebo capsule containing 500 mg microcrystalline cellulose

For co-administration with:
Maltodextrin 50 g dissolved in 150 ml water to be consumed within two minutes.

Intervention Type
Other

Primary outcome(s)
Incremental area-under-the-curve (IAUC) for plasma glucose concentration over 120 minutes. The glucose and insulin values will be measured every 15 mins for two hours eg. 0, 15, 30, 45, 60, 75, 90, 105, 120 mins at each visit.

Key secondary outcome(s))
1. IAUC for plasma insulin concentration over 120 minutes
2. IAUC for plasma glucose and insulin concentration over 120 minutes
3. Plasma glucose concentration at the nine timepoints
4. Plasma insulin concentration at the nine timepoints
5. Gastrointestinal tolerability - abdominal bloating may be experienced due to reduced

carbohydrate absorption. Gastrointestinal symptoms will be measured via questionnaire for 24 hours following each study visit

The glucose and insulin values will be measured every 15 mins for two hours eg. 0, 15, 30, 45, 60, 75, 90, 105, 120 mins at each visit.

Completion date
01/07/2014

Eligibility

Key inclusion criteria
1. Consent to study protocol
2. Age 18-65 years
3. BMI 20-30
4. Normal fasting glucose (fasting plasma glucose concentration <= 7.0 mmol/l)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
37

Key exclusion criteria
1. Previous diagnosis of impaired fasting glucose or impaired glucose tolerance
2. Type I/II diabetes mellitus
3. BMI <20 or >30
4. Alcohol consumption in the previous 12 hours
5. Current oral hypoglycaemic medication use
6. Pregnancy or breastfeeding
7. Symptomatic irritable bowel syndrome
8. Current participation in another clinical trial
9. History of renal or liver disease
10. History of clotting or bleeding disorders
11. Taken antibiotics in the last 3 weeks prior to screening

12. Taking daily medications or dietary supplements that are not suitable for the study in the opinion of the principal investigator and/or that are prohibited (as per protocol)
13. Known intolerance or allergy to mulberry extract or any ingredients in the study products

Date of first enrolment
01/01/2014

Date of final enrolment
01/07/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Southampton
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust (UK)

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
Technology Strategy Board Nutrition for Life (UK)

Results and Publications

Individual participant data (IPD) sharing plan

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	results	22/02/2017		Yes	No
Protocol article	protocol	28/10/2015		Yes	No
Dataset		22/02/2017	17/05/2023	No	No