ISRCTN99601810 https://doi.org/10.1186/ISRCTN99601810

A clinical trial to investigate the effect of a proprietary mulberry leaf extract (Reducose®) on lowering blood glucose rises after consuming a drink containing sugar (sucrose)

Submission date
12/10/2020

Recruitment status
No longer recruiting

Registration date
23/10/2020

Overall study status
Completed

Last Edited
13/08/2021

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The glycaemic index of foods shows how quickly each food affects your blood sugar (glucose) level when that food is eaten. Maintaining healthy blood glucose levels and avoiding large blood glucose spikes has a number of positive health benefits.

Previous clinical trials have shown that Reducose, a mulberry leaf extract can lower the glycaemic index of foods and lower the total blood glucose and blood glucose spikes after eating starch. This study will build on the clinical evidence on the health benefits of Reducose by evaluating the effects of a single dose of 250 mg of Reducose in blunting the blood glucose response after eating sugar (sucrose) and compare the results to a placebo arm where subjects only consume sucrose.

Who can participate?
40 healthy adults aged 18-60 with a BMI of 20-29.9.

What does the study involve?
Participants will be recruited to attend two study visits, at least 48 h apart, in order to test either 250 mg of Reducose mixed with 75 g sucrose (test), or 75 g sucrose alone (placebo). The test meal or placebo meal are packaged in opaque containers and dissolved in 250 ml water and are consumed. In the second visit, the product that has not yet been tested by the participant in the first visit will be prepared. The products are matched for taste and smell and neither participants nor the study team will be aware of the order that the test meals are given until all of the tests have been completed. Changes in blood glucose and insulin levels will be measured over 2 h.

What are the possible benefits and risks of participating?
Mulberry extract has an excellent safety profile and is widely consumed in Asia and is available as a dietary supplement in England. Previous clinical trials have shown that Reducose does not have any reported adverse reactions, a finding mirrored in the published literature. Participants

will have multiple finger pricks to test for blood glucose and insulin levels, therefore there will be a risk discomfort and bruising and a small risk of inflammation/infection at the site. Local infection control/procedures will be followed during each study visit.

Where is the study run from?
Oxford Brookes Centre for Nutrition and Health, Oxford Brookes University (UK)

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

Who is funding the study?
Phynova Group Ltd (UK)

Who is the main contact?
Andrew Gallagher
agallagher@phynova.com

Contact information

Type(s)
Scientific

Contact name
Mr Andrew Gallagher

ORCID ID
https://orcid.org/0000-0002-5974-4093

Contact details
16 Fenlock Court
Blenheim Office Park
Long Hanborough
United Kingdom
OX29 8LN
+44 (0)1993880700
agallagher@phynova.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SUGERS 1.1

Study information

Scientific Title
Clinical stUdy to assess the Glycaemic Effect of Reducose on a Sucrose challenge (SUGERS): a double blind, placebo controlled, crossover study

Acronym
SUGERS

Study objectives
1. Reducose® mulberry leaf extract, when co-administered with oral sucrose will reduce the incremental area under the curve (iAUC) for plasma glucose concentration over 120 minutes in normoglycaemic adults when compared to co-administration with placebo
2. Reducose®, when co-administered with oral sucrose, will not disproportionately increase the incremental area under the curve for plasma insulin concentration over 120 minutes in normoglycaemic adults compared to co-administration with placebo

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 07/03/2014, University Research Ethics Committee (UREC) at Oxford Brookes University (Research & Business Development Office, Directorate of Finance & Legal Services, Oxford Brookes University, Headington Campus, Gipsy Lane, Oxford, OX3 0BP, UK; +44 (0) 1865 48 4445; ethics@brookes.ac.uk), ref: 140806 (for glycaemic response),
2. Approved 24/01/2012, University Research Ethics Committee (UREC) at Oxford Brookes University (Research & Business Development Office, Directorate of Finance & Legal Services, Oxford Brookes University, Headington Campus, Gipsy Lane, Oxford, OX3 0BP, UK; +44 (0) 1865 48 4445; ethics@brookes.ac.uk), ref: 110594 (for insulinaemic response)

Study design
Double-blind, randomised, repeat measure, crossover design trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Postprandial glycaemic control

Interventions
The trial has a randomised crossover design and so each subject would act as their own control. Randomisation sequence was generated using www.randomization.com using the randomly permuted blocks method to assign which treatment subjects would receive first. Researchers recruiting the participants were unaware of the allocation sequence (concealed allocation). Participants were assigned to a participant number according to their chronological order of enrolment in the study. The allocated participant number was used to identify the participants and their corresponding intervention sequence.

Participants will be recruited to attend two study visits, with at least 48 h apart for washout. The study will evaluate a single dose of 250 mg mulberry leaf extract (Reducose) against matched

placebo. The mulberry leaf extract is standardised to contain 5% (m/m) 1-deoxynojirimycin (DNJ). Each 250 mg dose contains 12.5 mg DNJ.

Test product contained 250 mg Reducose mulberry leaf extract directly blended into 75 g sucrose. Placebo product contained 75 g sucrose alone. Reducose has minimal impact on taste, smell, and colour of the sucrose blend. The test meal or placebo meal are packaged in opaque containers and dissolved in 250 ml water and are consumed. The participants and study team are blind to allocation.

At each study visit, plasma insulin and glucose concentrations will be measured by fingerprick blood sample at 0, 15, 30, 45, 60, 90, and 120 min.

Intervention Type
Supplement

Primary outcome(s)
Incremental area under curve for plasma glucose concentration over 120 min, plasma glucose concentration collected by fingerprick blood sample at 0, 15, 30, 45, 60, 90, and 120 min

Key secondary outcome(s))
Incremental area under curve for plasma insulin concentration over 120 min, plasma insulin concentration collected by fingerprick blood sample at 0, 15, 30, 45, 60, 90, and 120 min

Completion date
15/08/2016

Eligibility

Key inclusion criteria
1. Consent to study protocol
2. Aged 18-60 years
3. BMI 20-29.9 kg/m²
4. Fasting blood glucose <6.1 mmol/l

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex

All

Total final enrolment
40

Key exclusion criteria
1. Pregnant or lactating
2. Any known food allergies or intolerance to mulberry leaf extracts
3. Presence of a medical condition, or taking medication known to affect glucose regulation and /or influence digestion and absorption of nutrients
4. History of diabetes mellitus (type I or type II), or the use of antihyperglycaemic drugs or insulin to treat diabetes or related conditions
5. Use of steroids, protease inhibitors, or antipsychotics which would affect glucose metabolism and body fat distribution

Date of first enrolment
21/03/2016

Date of final enrolment
04/08/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford Brookes Centre for Nutrition and Health
Oxford Brookes University
Headington Campus
Oxford
United Kingdom
OX3 0BP

Sponsor information

Organisation
Phynova Group Limited

Funder(s)

Funder type

Industry

Funder Name
Phynova Group Limited

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available to researchers upon request from Phynova Group Limited. Anonymised patient level data will be available for research purposes within six months of publishing the results of the primary endpoints, key secondary endpoints and safety data in a peer-reviewed journal. As participants only consented for their data to be used to investigate a particular health benefit of the test product, access to data will only be provided for researchers that are investigating the same or an equivalent product for the same health benefit. Data will be made available on request provided Phynova has the legal authority to provide the data; for example, if Phynova has out-licensed the data to another company then it would no longer have the legal authority to provide the data. Data will only be made available if Phynova is able to anonymise the data without compromising the confidentiality and privacy of research participants. Data from clinical trials where the data labels and/or supporting documents are not in English will only be made available in their original format and no translations will be provided. The following information will be made available: raw dataset excluding any patient images, protocol with any amendments, analysis and reporting plan. Researchers requesting access to data should email their requests to info@phynova.com and should include a description of the intended research.

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		15/04/2021	13/08/2021	Yes	No
Participant information sheet	version v3.0	06/03/2014	23/10/2020	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes