

Blackcurrant juice study: a study to investigate the biokinetics and effects of a blackcurrant juice on endothelial function

Submission date

06/08/2010

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

18/08/2010

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

14/11/2011

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Michael Gordon

Contact details

Hugh Sinclair Unit of Human Nutrition,
Department of Food and Nutritional Sciences,
The University of Reading,
Whiteknights, PO Box 226,
Reading
United Kingdom
RG6 6AP
+44 (0)118 3786723
m.h.gordon@reading.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RDGJUICE08

Study information

Scientific Title

A double blind, randomised, placebo controlled, cross-over study to investigate the biokinetics and effects of a blackcurrant juice on endothelial function

Study objectives

Consumption of 250 ml of a 20% blackcurrant juice drink provides phytochemicals that are absorbed and improve endothelial function in an acute study

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Research Ethics Committee of the University of Reading approved on the 12th of July 2007 (ref: Project 07/26)

Study design

Randomised double blind placebo controlled crossover acute meal study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Absorption of phytochemicals and effects on endothelial function

Interventions

One dose of 250 ml of a 20% blackcurrant juice drink in comparison with a control drink lacking flavonoids.

The washout period between the intervention and control dose was 1 month.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Endothelial function/vascular reactivity assessed by laser doppler iontophoresis at 0 and 120 minutes.

Secondary outcome measures

Phytochemical composition (phenolic acids and flavonoids) of plasma and urine was measured at 0.5 hour intervals for the first 4 hours, then 1 hour intervals up to 8 hours. A 24 hour urine sample was also analysed.

Overall study start date

04/12/2007

Completion date

05/06/2008

Eligibility**Key inclusion criteria**

1. Men and women between the ages of 30-70 years
2. Normal weight
3. Drink no more than 15 units of alcohol (i.e. not more than 7 pints) per week
4. Not regularly undertaking vigorous exercise or fitness training (i.e. not more than 3, 20 minute aerobic sessions per week)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

20

Key exclusion criteria

1. Diabetes
2. Heart disease
3. Gall bladder problems
4. Phenylketonuria (PKU)
5. Known food allergies or intolerances or abnormalities of fat metabolism
6. Trying to lose weight or following other diets
7. Taking dietary supplements
8. Hormone abnormalities or liver disease

9. Regularly use certain types of medication

10. Pregnant, lactating or, if female and of reproductive age, not using a reliable form of contraception (including abstinence)

Date of first enrolment

04/12/2007

Date of final enrolment

05/06/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Hugh Sinclair Unit of Human Nutrition,

Reading

United Kingdom

RG6 6AP

Sponsor information

Organisation

GlaxoSmithKline Nutritional Healthcare (UK)

Sponsor details

980 Great West Road

Brentford

United Kingdom

TW8 9GS

Sponsor type

Industry

ROR

<https://ror.org/01xsqw823>

Funder(s)

Funder type

Industry

Funder Name

SmithKline Beecham plc (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2011		Yes	No