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

Submission date	Recruitment status
06/08/2010	No longer recruiting
Registration date	**Overall study status**
18/08/2010	Completed
Last Edited	**Condition category**
14/11/2011	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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)

Primary study design
Interventional

Study design
Randomised double blind placebo controlled crossover acute meal study

Study type(s)
Quality of life

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

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre

Hugh Sinclair Unit of Human Nutrition,
Reading
United Kingdom
RG6 6AP

Sponsor information

Organisation
GlaxoSmithKline Nutritional Healthcare (UK)

ROR
https://ror.org/01xsqw823

Funder(s)

Funder type
Industry

Funder Name
SmithKline Beecham plc (UK)

Results and Publications

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