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Evaluation of the bioavailability of bioactive wheat bran components

Submission date 17/09/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/12/2008	**Overall study status** Completed	
Last Edited 04/03/2016	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.healthgrain.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluation of the bioavailability of bioactive wheat bran components

Study objectives
Bioactive components present in minimally processed wheat grain fractions are available to the body and can be detected in the plasma and urine shortly after consumption.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the University of Ulster Research Ethics Committee in July 2006 (ref: REC/06/0012).

Study design
Randomised cross-over design on three occasions carried out in a single-centre

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Chronic diseases, particularly cardiovascular disease and cancers

Interventions
1. Test-meal 1: 50 g wheat bran boiled in water with sugar
2. Test-meal 2: 50 g wheat aleurone boiled in water with sugar
3. Control-meal: 50 g refined wheat product

Test and control meals were balanced for energy, fibre and macronutrients.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Bioactive wheat bran

Primary outcome measure
1. Changes in plasma betaine, choline, folate, tocopherols and ferulic acid attributable to treatments, measured at baseline, 0.5 hours, 1 hour, 2 hours and 3 hours post-meal
2. Changes in urinary ferulic acid attributable to treatments, measured at baseline, 0.5 hours, 1 hour, 2 hours, 3 hours and 4 hours post-meal

Secondary outcome measures
1. Changes in plasma antioxidant activity attributable to treatments, measured at baseline, 0.5 hours, 1 hour, 2 hours and 3 hours post-meal
2. Changes in urinary antioxidant activity and phenolic activity attributable to treatments, measured at baseline, 0.5 hours, 1 hour, 2 hours, 3 hours and 4 hours post-meal

Overall study start date
01/04/2006

Completion date
31/05/2006

Eligibility

Key inclusion criteria
Healthy 18 - 40 year old men and women with Body Mass Index (BMI) between 18 and 30 kg/m^2.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
14 (7 males; 7 females)

Key exclusion criteria
1. Smokers
2. Individuals with diabetes
3. Pre-existing chronic disease

4. On any prescription medicine
5. Individuals who regularly take any vitamin or mineral supplement or did so in the 6 months prior to the study
6. Gluten or wheat intolerant individuals
7. Pregnant or lactating women
8. Individuals who have given blood to the Blood Transfusion Service (BTS) in the 6 months prior to the study

Date of first enrolment
01/04/2006

Date of final enrolment
31/05/2006

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Northern Ireland Centre for Food and Health (NICHE)
Coleraine
United Kingdom
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Sponsor information

Organisation
European Commission (Belgium)

Sponsor details
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Sponsor type
Government

Website
http://www.healthgrain.org

ROR
https://ror.org/00k4n6c32

Funder(s)

Funder type
Government

Funder Name
HEALTHGRAIN (Europe) - an integrated 6th framework European Union (EU) project (ref: FOOD-CT-2005-514008)

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	17/02/2016		Yes	No