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Evaluation of the bioavailability of bioactive wheat bran components from bread rolls

Submission date	Recruitment status
17/09/2008	No longer recruiting
Registration date	**Overall study status**
04/12/2008	Completed
Last Edited	**Condition category**
04/03/2016	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

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 from bread rolls

Study objectives
Bioactive components present in processed wheat grain fraction enriched bread rolls 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)
University of Ulster Research Ethics Committee, May 2006, ref: REC/06/0036

Study design
Randomised within subject 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)
Prevention

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 aleurone incorporated into a bread roll
2. Test-meal 2: 50 g wheat aleurone + 5.2 mg iron incorporated into a bread roll
3. Control-meal: 50 g refined wheat product incorporated into a bread roll

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

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Wheat grain

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
3. Evaluation of the effects of processing, including iron fortification, on the availability of the bioactive components in wheat fractions, using test-meal 2 and comparisons with previous work

Overall study start date
01/01/2007

Completion date
31/03/2007

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
13 (6 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 4 months prior to the study

Date of first enrolment
01/01/2007

Date of final enrolment
31/03/2007

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 EU project (ref: FOOD-CT-2005-514008)

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/12/2013

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	14/02/2015		Yes	No