

Effects of wholegrain components on metabolic biomarkers: a four-week intervention study in 'at risk' subjects

Submission date 03/09/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 04/12/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/07/2012	Condition category Other	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Study objectives

Long-term consumption of bran-rich cereal products impacts favourably on risk factors for heart disease and metabolic syndrome in apparently healthy, 'at risk' men and women.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was approved by the University of Ulster Research Ethics Committee in March 2007 (ref: REC/07/0016).

Study design

Single centre randomised single blind parallel controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

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

Volunteers were stratified by age and sex and randomly assigned into the test or control group:

1. Test group: 3 x high-bran products per day for 4 weeks (1 x ready-to-eat cereal + 2 x bread products)
2. Control group: 3 x refined high-fibre products per day for 4 weeks (1 x ready-to-eat cereal + 2 x bread products)

Test and control products were balanced for energy, fibre and macronutrients and incorporated by volunteers into their normal diet.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Bran-rich cereal products

Primary outcome measure

Changes in plasma homocysteine (a risk marker for CHD) attributable to treatment during the intervention, measured at baseline and 4 weeks.

Secondary outcome measures

Changes in other risk markers for disease attributable to treatments during the intervention:

1. Inflammatory markers and endothelial function
2. Antioxidant status
3. Lipid profile
4. Relevant micronutrient levels
5. Insulin and glucose levels

Outcomes measured at baseline and 4 weeks.

Overall study start date

15/12/2007

Completion date

04/06/2008

Eligibility

Key inclusion criteria

1. Healthy men and women aged between 45 - 65 years
2. Body Mass Index (BMI) greater than 25 kg/m²

This inclusion criteria were selected as such individuals are thought to be at a slightly greater risk of chronic disease.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

80 volunteers (40 males; 40 females); 40 controls, 40 on test treatment

Key exclusion criteria

1. Smokers
2. People on special diets (e.g. vegetarians, coeliac patients)
3. People with diabetes
4. Pre-existing chronic disease
5. Regular use of prescription medicine, including statins and blood pressure medication
6. People who regularly take any vitamin or mineral supplement or have done so in the last 6 months
7. Women who are pregnant or lactating
8. People who have given blood to the blood transfusion service (BTS) within the past 4 months

Date of first enrolment

15/12/2007

Date of final enrolment

04/06/2008

Locations

Countries of recruitment

Northern Ireland

United Kingdom

Study participating centre

Northern Ireland Centre for Food and Health (NICHE)

Coleraine

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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	14/11/2012		Yes	No