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An investigation of the functional significance of marginal riboflavin status in young women

Submission date	Recruitment status	[_] Prospectively registered
25/05/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/08/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/01/2018	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.riboflavin.group.shef.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
University Research Ref No.: 109242

Study information

Scientific Title
An investigation of the functional significance of marginal riboflavin status in young women

Acronym
RiboFem

Study objectives
National Diet and Nutrition Surveys show that in certain groups of the population there is a high proportion of people with biochemical evidence of poor riboflavin status. The functional significance of this is not clear.

We will examine the hypothesis that marginal riboflavin status is associated with impaired handling of iron. The results will help to clarify the functional significance of marginal riboflavin status and inform debate regarding dietary recommendations for this nutrient.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Sheffield University Research Ethics Committee on the 15th March 2006 (ref: SMBRER15).

Study design
Randomised double-blind placebo controlled interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet
Participant information sheet can be located at: http://www.riboflavin.group.shef.ac.uk /riboflavininfosheet.pdf

Health condition(s) or problem(s) studied
Impaired handling of iron

Interventions

Main study:
Three intervention groups:
1. 2 mg riboflavin for eight weeks
2. 4 mg riboflavin for eight weeks
3. Placebo for eight weeks

Bioavailability study:
32 volunteers from the main study randomly assigned to participate in additional bioavailability study involving consumption of special meals two weeks before and immediately after the main study. These meals will contain a stable isotope of iron (Fe58).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Riboflavin

Primary outcome measure
Main study, measured at baseline and after eight weeks intervention:
1. Measures of iron and haematological status:
1.1. Ferritin
1.2. Haemoglobin
1.3. Mean Corpuscular Volume (MCV)
1.4. Mean Corpuscular Haemoglobin Concentration (MCHC)
1.5. Red Blood Cells (RBC)
1.6. Haematocrit
1.7. Zinc Protoporphyrin (ZPP)
1.8. Soluble Transferrin Receptor (sTFR)

Bioavailability study, additional outcomes measured at baseline and two weeks after dose of isotopic iron (repeated on two separate occasions before and after main study):
Incorporation of Fe58 into erythrocytes.

Secondary outcome measures
Lowering of plasma homocysteine.

Overall study start date
01/04/2006

Completion date
30/12/2007

Eligibility

Key inclusion criteria
1. Women aged 19 to 25 years
2. Low milk consumption (less than 200 ml a day)

3. Healthy
4. Marginal riboflavin deficiency as measured by an Erythrocyte Glutathione Reductase Activation Coefficient of greater than 1.4

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
120

Key exclusion criteria
1. Use of multivitamin or iron supplements (within last three months)
2. Diagnosed gastrointestinal disorders
2.1. coeliac disease
2.2. ulcerative colitis
2.3. Crohns disease
2.4. inflammatory bowel disease
3. Blood donors
4. Haemochromatosis
5. Pregnancy

Date of first enrolment
01/04/2006

Date of final enrolment
30/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Human Nutrition Unit
Sheffield
United Kingdom
S10 2RX

Sponsor information

Organisation
University of Sheffield (UK)

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Research Office
New Spring Road
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United Kingdom
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Sponsor type
University/education

Website
http://www.shef.ac.uk/

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Government

Funder Name
Food Standards Agency (UK) (ref: N05061)

Alternative Name(s)
The Food Standards Agency, FSA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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?
Protocol article	protocol	26/03/2009		Yes	No
Results article	results	01/06/2011		Yes	No