ISRCTN23620802 https://doi.org/10.1186/ISRCTN23620802

Does the B-vitamin riboflavin lower blood pressure in individuals with high blood pressure who have a specific genetic make up?

Submission date
26/09/2011

Recruitment status
No longer recruiting

Registration date
02/02/2012

Overall study status
Completed

Last Edited
02/09/2015

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Around 10% of the population have a particular genetic make-up (known as the TT genotype) which may increase their risk of having high blood pressure (hypertension). Studies have shown that taking riboflavin (vitamin B2) supplements can decrease blood pressure specifically in premature heart disease patients with the TT genotype. The aim of this current study is to examine whether riboflavin can decrease blood pressure in patients with high blood pressure and the TT genotype generally.

Who can participate?
Patients who previously took part in two ongoing studies at our centre and identified as having both high blood pressure and the TT genotype.

What does the study involve?
Participants will be randomly allocated to take either riboflavin or placebo (dummy) tablets for 16 weeks.

What are the possible benefits and risks of participating?
If the results of this study show that riboflavin can lower blood pressure in people with the TT genotype then this could have important implications for the management and treatment of high blood pressure in this specific group.

Where is the study run from?
University of Ulster (UK).

When is the study starting and how long is it expected to run for?
May 2010 to January 2013.

Who is funding the study?
1. University of Ulster (UK)
2. DSM Nutritional Products Ltd (UK)

Who is the main contact?
Dr Mary Ward

Contact information

Type(s)
Scientific

Contact name
Dr Mary Ward

Contact details
University of Ulster
Cromore Road
Coleraine, County Londonderry
United Kingdom
BT52 1SA

Additional identifiers

Study information

Scientific Title
An interventional study to investigate the effect of riboflavin supplementation (1.6mg/d /16weeks) on blood pressure in hypertensive individuals who are homozygous for the 677Câ T polymorphism (TT genotype) in the gene encoding the enzyme methylenetetrahydrofolate reductase (MTHFR)

Study objectives
Riboflavin supplementation will result in a significant decrease in blood pressure in a specific group of hypertensive patients.

The aim of this study is to determine if riboflavin can lower blood pressure in hypertensive patients with the TT genotype. This will be achieved by conducting a double-blind placebo-controlled intervention study (1.6mg/day riboflavin or placebo for 16 weeks).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Northern Ireland, 13/01/2010, ref: 09/NIR01/68

Primary study design
Interventional

Study design
Randomised placebo-controlled double-blind trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Hypertension

Interventions
Double-blind randomised controlled riboflavin (1.6mg/d/16 weeks) placebo-controlled trial in hypertensive individuals with the TT genotype

Intervention Type
Supplement

Primary outcome(s)
Blood pressure

Key secondary outcome(s)
Riboflavin status

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. Individuals recruited previously who consented to being contacted regarding future studies
2. Individuals identified as having the TT genotype

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. A history of gastrointestinal, hepatic, renal or haematological disorders
2. Are taking B vitamin supplements, anticonvulsant therapy or any other drugs known to interfere with folate / B vitamin metabolism

Date of first enrolment
01/05/2010

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
University of Ulster
Coleraine, County Londonderry
United Kingdom
BT52 1SA

Sponsor information

Organisation
University of Ulster (UK)

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
University/education

Funder Name
University of Ulster (UK)

Alternative Name(s)
University of Ulster, Ulster, Ulster Uni, Ollscoil Uladh, Ulstèr Universitie, Ulstèr Varsitie, UU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
DSM Nutritional Products Ltd (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	01/06/2013		Yes	No