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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
26/09/2011	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
02/02/2012	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
02/09/2015	Circulatory System	

#### 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)

## **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

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers N/A

## 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 placebocontrolled 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

#### Study design

Randomised placebo-controlled double-blind trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Treatment

#### 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

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 measure

Blood pressure

#### Secondary outcome measures

Riboflavin status

#### Overall study start date

01/05/2010

#### 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**

#### Age group

Adult

#### Sex

Both

#### Target number of participants

Total recruitment target n=80

#### 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

Northern Ireland

United Kingdom

## Study participating centre University of Ulster

Coleraine, County Londonderry United Kingdom BT52 1SA

## **Sponsor information**

#### Organisation

University of Ulster (UK)

#### Sponsor details

c/o Mr Nick Curry Shore Road Newtonabbey, County Antrim Northern Ireland

#### United Kingdom BT37 OQB

#### Sponsor type

University/education

#### Website

http://www.ulster.ac.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, 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**

#### 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	01/06/2013		Yes	No