

Genetic polymorphisms in a beta-carotene metabolising enzyme

Submission date 12/05/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/05/2010	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 31/10/2019	Condition category Other	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Georg Lietz

Contact details
School of Agriculture, Food and Rural Development (AFRD)
University of Newcastle
Kings Road
Newcastle upon Tyne
United Kingdom
NE1 7RU

Additional identifiers

Protocol serial number
7413

Study information

Scientific Title
Do genetic polymorphisms in a beta-carotene metabolising key enzyme influence dietary vitamin A requirements?

Study objectives

Vitamin A (retinol) is an essential nutrient for vision, embryonic development, maturity of organs, cellular proliferation and the immune response. It is obtained from the diet *per se* or through provitamin A sources that are cleaved enzymatically in the body to produce retinol. Vitamin A deficiency occurs largely due to increases in physiological requirements (growth, pregnancy, lactation, infection) together with a low dietary intake.

Currently, the mean daily intake of vitamin A is below the recommended intake levels for men and women aged 19 to 24 years. This means that young individuals in the UK rely to over 50% on provitamin A sources, beta-carotene being the main one, to cover their vitamin A needs. Since a significant proportion of young British individuals have a low vitamin A intake and since the Expert Group on Vitamins and Minerals has recommended to limit the use of beta-carotene in food supplements, there is growing concern that young men and women in the UK might develop subclinical deficiencies, therefore increasing their susceptibility to infectious diseases. This concern is especially valid for young pregnant women who will experience a higher physiological need for vitamin A.

Given the fact that a high proportion of the British population relies on beta carotene to cover their vitamin A needs, it is important to note that the amount of retinol produced after ingestion and conversion of beta-carotene is highly variable between healthy individuals. Several studies have shown a large disparity between individuals who are efficient or inefficient converters of beta-carotene, with variations of up to 8-fold. It is possible that the observed differences in obtaining retinol from beta-carotene may be due to genetic polymorphisms in genes involved in aspects of beta-carotene conversion. Indeed, results from our laboratory have shown that two genetic variants exist in the key enzyme responsible for beta-carotene conversion.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Newcastle and North Tyneside Local Research Ethics Committees approved on the 19th May 2009 (ref: 09/H0904/20)

Study design

Single centre non-randomised interventional trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Public Health Research

Interventions

The intervention will last 14 days. However, first contact with the study participants will be 2 months prior to the start of the intervention to explain the study. A capsule containing 2 mg

dose of beta-carotene and 1 mg retinyl acetate stable isotope will be orally administered to volunteers on day 1. Blood samples will be drawn at 7 time points on day 1, with subsequent samples being taken on days 2, 3, 7, and 14.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Blood concentrations of administered beta-carotene/retinyl acetate, and derived metabolites. Primary outcome measures will be taken at 0, 2, 4, 6, 8, 12 hours on day 1. Then at days 2, 3, 7, and 14.

Key secondary outcome(s)

No secondary outcome measures

Completion date

30/06/2010

Eligibility**Key inclusion criteria**

1. Aged 18 - 45 years
2. Generally fit and healthy adults
3. Males and females

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Smokers
2. Pregnant females
3. Diabetics
4. Liver disease
5. Gastrointestinal disorders

Date of first enrolment

01/09/2009

Date of final enrolment

30/06/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

School of Agriculture, Food and Rural Development (AFRD)

Newcastle upon Tyne

United Kingdom

NE1 7RU

Sponsor information

Organisation

Newcastle University (UK)

ROR

<https://ror.org/01kj2bm70>

Funder(s)

Funder type

Research council

Funder Name

Biotechnology and Biological Science Research Council (BBSRC) (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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes