Genetic polymorphisms in a beta-carotene metabolising enzyme

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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 exists 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

Secondary study design Non randomised controlled trial

Study setting(s) Other

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

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 adminstered 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 measure

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.

Secondary outcome measures No secondary outcome measures

Overall study start date 01/09/2009

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

Age group Adult

Lower age limit

18 Years

Sex Both

Target number of participants Planned sample size: 200

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 England

United Kingdom

Study participating centre School of Agriculture, Food and Rural Development (AFRD) Newcastle upon Tyne United Kingdom NE1 7RU

Sponsor information

Organisation Newcastle University (UK)

Sponsor details School of Agriculture Food and Rural Department Claremont Road Newcastle Upon Tyne England

United Kingdom NE1 7RU

Sponsor type University/education

Website http://www.ncl.ac.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

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