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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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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 andthe 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

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 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(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