

Effect of a dietary intervention on Functional Immune sTatus in the elderly

Submission date
24/05/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
13/08/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
05/11/2010

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N05068

Study information

Scientific Title

Acronym

The FIT study

Study objectives

We hypothesise that:

1. There is a relationship between nutritional status, dietary intake and immune function in the elderly
2. Improving nutritional status will enhance immune function in the elderly

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Barnsley Research Ethics Committee on the 10th October 2005 (ref: 05/Q2304/48).

Study design

Randomised, controlled, single centre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

This study looks at immune function in healthy subjects

Interventions

Volunteers will be randomised to one of three intervention groups:

1. Dietary intervention: volunteers will be asked to consume a diet aimed at increasing the intake of fruit and vegetables (to five portions/day), fish (to two portions/week), and to increase consumption of wholemeal bread and nuts
2. Micronutrient supplement: vitamin C, beta carotene, zinc, selenium, vitamin E
3. Placebo

Each intervention will be for three months. Volunteers will be followed up for three months post-intervention.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Innate and adaptive immunity, measured using:
 - 1.1. High-Sensitivity C-Reactive Protein (hSCRP)
 - 1.2. Natural killer cell cytotoxicity
 - 1.3. Neutrophil and monocyte oxidative burst and phagocytic activity
 - 1.4. T-cell activation
 - 1.5. Reponse to tetanus vaccine (administered at eight weeks)
2. Nutritional status, measured by:
 - 2.1. Plasma carotenoids
 - 2.2. Retinol
 - 2.3. Vitamin E
 - 2.4. Ascorbic acid
 - 2.5. Selenium
 - 2.6. Glutathione peroxidase
 - 2.7. Zinc
3. Number of days infection, measured using a self-reported infection diary

The primary and secondary outcomes will be measured at baseline, end of intervention and three months post-intervention, with the exception of the response to tetanus vaccine which is measured at 8 weeks and 12 weeks only (coinciding with tetanus vaccination and end of intervention).

Secondary outcome measures

1. Dietary intake and dietary change, measured using three-day food diaries
2. Physical activity, measured with the Community Healthy Activities Model Program for Seniors (CHAMPS) physical activity questionnaire
3. Quality of life, measured using the 36-item Geriatric Depression Scale (GDS36)
4. Body composition, measured by body weight, height, triceps skin-fold thickness

The primary and secondary outcomes will be measured at baseline, end of intervention and three months post-intervention.

Overall study start date

01/04/2006

Completion date

31/03/2009

Eligibility

Key inclusion criteria

1. Men and women
2. Community based healthy volunteers
3. Aged 65 to 85 years
4. Living an active independent life
5. Low intake of fruit and vegetables (less than or equal to two portions per day)

Participant type(s)

Healthy volunteer

Age group

Senior

Sex

Both

Target number of participants

216

Key exclusion criteria

1. Hospitalised within past 12 months
2. Current or recent (within three months) users of micronutrient supplements
3. Have a Body Mass Index (BMI) less than 18 or more than 30
4. Have a special diet or about to embark on a weight loss diet
5. Have a malignancy or severe medical or psychiatric illness
6. Cannot understand or communicate effectively
7. Have insulin-dependent diabetes mellitus

Date of first enrolment

01/04/2006

Date of final enrolment

31/03/2009

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Human Nutrition Unit

Sheffield

United Kingdom

S10 2JX

Sponsor information

Organisation

The University of Sheffield (UK)

Sponsor details

Research Office
Research Services
New Spring House
231 Glossop Road
Sheffield
England
United Kingdom
S10 2GW
+44 (0)114 222 1469
research.office@sheffield.ac.uk

Sponsor type

University/education

Website

<http://www.shef.ac.uk>

ROR

<https://ror.org/05krs5044>

Funder(s)**Funder type**

Government

Funder Name

Food Standards Agency (UK) (ref: N05068)

Alternative Name(s)

The Food Standards Agency, FSA

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

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	22/02/2010		Yes	No