ISRCTN21676269 https://doi.org/10.1186/ISRCTN21676269

The effect of dietary intake of Fruit and Vegetables on vascular function in type two Diabetes mellitus

Submission date	Recruitment status
12/05/2008	No longer recruiting
Registration date	**Overall study status**
20/11/2008	Completed
Last Edited	**Condition category**
17/01/2014	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RGHT000151

Study information

Scientific Title

Acronym
FVD Study

Study objectives
To determine the effect of fruit and vegetable supplementation on measures of vascular function and oxidative stress in type two diabetes mellitus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the Queens University Belfast Research Ethics Committee in December 2003 (ref: 391/03)

Study design
Randomised, single centre, controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

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
Type two diabetes and vascular disease

Interventions
There is a four-week washout period where all 80 subjects take only one portion of fruit and vegetables per day. The subjects are then randomised to either one or six portions of fruit or vegetables for the next eight weeks. The total duration of the trial is 12 weeks for each subject.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Change in endothelial function as measured by venous occlusion plethsymography and pulse wave analysis/velocity.

Secondary outcome measures
Change in biochemical measures of vascular function:
1. Total cholesterol
2. High density lipoprotein (HDL)-cholesterol
3. High sensitivity C-reactive protein (CRP)
4. Triglycerides
5. Plasma plasminogen activator inhibitor-1 (PAI-1)
6. Von Willebrand Factor
7. Plasma glucose
8. Serum insulin
9. HbA1c
10. Adhesion molecules

The subjects undergo assessment of vascular function at the end of the four-week washout period and the eight-week intervention period.

Overall study start date
01/11/2005

Completion date
01/06/2008

Eligibility

Key inclusion criteria
1. Male or female
2. Aged 40 - 70 years
3. Type two diabetes on diet and/or oral hypoglycaemic therapy

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria

1. Any acute coronary event or surgery within the previous three months
2. Pregnant or lactating
3. Excess alcohol consumption (greater than 2 units/day for women, greater than 3 units/day for men)
4. Food sensitivities that would interfere with tolerance of fruit and vegetable consumption
5. Medical conditions that would substantially limit their ability to complete the study requirements
6. Ingestion of oral vitamins within the previous four weeks

Date of first enrolment
01/11/2005

Date of final enrolment
01/06/2008

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Regional Centre for Endocrinology and Diabetes
Belfast
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BT12 6BA

Sponsor information

Organisation
Royal Victoria Hospital (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03rq50d77

Funder(s)

Funder type
Government

Funder Name
The Research and Development Office of Northern Ireland (UK) (ref: EAT/2933/04)

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	14/01/2014		Yes	No