

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

Submission date 12/05/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/11/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/01/2014	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Quality of life

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(s)

Change in endothelial function as measured by venous occlusion plethysmography and pulse wave analysis/velocity.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

Northern Ireland

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

Sponsor information

Organisation
Royal Victoria Hospital (UK)

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

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