

# 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

☐ Prospectively registered

☐ Protocol

**Registration date**  
20/11/2008

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
17/01/2014

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ 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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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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 plethysmography 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

United Kingdom

BT12 6BA

## Sponsor information

**Organisation**

Royal Victoria Hospital (UK)

**Sponsor details**

Royal Research Office

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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?
<a href="#">Results article</a>	results	14/01/2014		Yes	No