

Towards a more cost-effective diabetes control in primary care: the EFFIMODI (EFFicient MOnitoring of Diabetes) trial

| | | |
|--|--|--|
| Submission date 02/06/2009 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 14/07/2009 | Overall study status Completed | <input checked="" type="checkbox"/> Protocol |
| Last Edited 25/04/2014 | 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

Contact name

Miss Paulien Renske Wermeling

Contact details

University Medical Center Utrecht
Julius Center for Health Sciences and Primary Care
P.O. Box 85500
Utrecht
Netherlands
3508 GA
+31 (0)88 75 686 40
P.Wermeling@umcutrecht.nl

Additional identifiers

Protocol serial number

80-82310-98-09058

Study information

Scientific Title

Six-monthly monitoring compared with three-monthly monitoring in type 2 diabetes mellitus: a randomised, controlled, patient-preference equivalence trial in primary care

Acronym

EFFIMODI

Study objectives

As of 30/03/2010 this record has been updated; all changes can be found in the relevant field with the above update date.

Current primary objective as of 30/03/2010:

Does six-monthly monitoring of well controlled people with type 2 diabetes mellitus (DM2) in primary care lead to equivalent cardiometabolic control as three-monthly monitoring?

Initial primary objective at time of registration:

Does six-monthly monitoring of well controlled people with type 2 diabetes mellitus (DM2) in primary care lead to equivalent glycaemic control as three-monthly monitoring?

Secondary objectives:

1. What are the costs of six-monthly follow up of DM2 patients compared with three-monthly follow up?
2. In case the three-monthly follow up is more effective than the six-monthly follow up: what is the incremental cost-effectiveness of three-monthly versus six-monthly follow up of DM2 patients in general practice?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Research Ethics Committee (MREC) Utrecht approved on the 17th March 2009 (ref: 08-453, CCMO number: NL25787 041 08)

Study design

Single centre randomised controlled patient-preference equivalence trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Type 2 diabetes mellitus

Interventions

Control: three-monthly diabetes monitoring by general practitioner and practice nurse

Intervention: six-monthly diabetes monitoring by general practitioner and practice nurse

The intervention will last one and a half year.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Current information as of 30/03/2010:

Percentage of people that remains under good cardiometabolic control, defined as having HbA1c less than or equal to 7.5% and systolic blood pressure less than or equal to 145 mmHg and total cholesterol less than or equal to 5.2 mmol/l. HbA1c, systolic blood pressure and total cholesterol will be collected from the general practitioners' Information System.

Initial information at time of registration:

Change in glycaemic control, expressed as the mean change in HbA1c percentage between baseline and follow-up. HbA1c will be collected from the general practitioners' Information System.

Key secondary outcome(s)

Differences in:

1. Blood pressure, collected from the general practitioners Information System
2. Body mass index, collected from the general practitioners Information System
3. Cholesterol, collected from the general practitioners Information System
4. Fasting blood glucose, collected from the general practitioners Information System
5. Lifestyle factors (smoking behaviour, physical activity), measured using the SQUASH questionnaire before and after the intervention period
6. Patients' quality of life, measured using the 36-item Short Form Health Survey (SF-36) and EuroQoL questionnaire (EQ5D) before and after the intervention period
7. Diabetes-specific distress, measured using the Problem Areas In Diabetes (PAID) questionnaire before and after the intervention period
8. Satisfaction with care, measured using the Diabetes Treatment Satisfaction Questionnaire (DTSQ) before and after the intervention period
9. Adherence with medications, collected from the general practitioners Information System

Added as of 30/03/2010:

10. HbA1c, collected from the general practitioners' Information System

Completion date

01/06/2011

Eligibility**Key inclusion criteria**

1. People with DM2
2. Aged 40 - 80 years, either sex
3. Treated by their general practitioner

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Contraindications for less frequent than three-monthly monitoring:

1. Duration of DM2 for less than one year
2. Insulin treatment
3. HbA1c greater than 7.5%
4. Systolic blood pressure greater than 145 mmHg
5. Total cholesterol greater than 5.2 mmol/L

Date of first enrolment

16/04/2009

Date of final enrolment

01/06/2011

Locations**Countries of recruitment**

Netherlands

Study participating centre

University Medical Center Utrecht

Utrecht

Netherlands

3508 GA

Sponsor information**Organisation**

University Medical Center Utrecht (UMCU) (Netherlands)

ROR

<https://ror.org/0575yy874>

Funder(s)**Funder type**

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)
(ref: 80-82310-98-09058)

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 | satisfaction results | 30/07/2013 | | Yes | No |
| Results article | results | 01/09/2014 | | Yes | No |
| Protocol article | protocol | 11/05/2010 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |