Effect of self-monitoring of glucose in noninsulin treated patients with type two diabetes

Submission date 02/05/2007

Recruitment statusNo longer recruiting

Registration date

Overall study status

02/05/2007

Completed

Last Edited

Condition category

29/12/2016 Nutritional, Metabolic, Endocrine

[X] Results

[X] Protocol

Individual participant data

[X] Prospectively registered

[] Statistical analysis plan

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

NTR807

Study information

Scientific Title

The effect of self monitoring of blood glucose and urine glucose relative to usual care without self monitoring on diabetes related distress and glycaemic control in patients with type 2 diabetes who are not using insulin

Acronym

IN CONTROL

Study objectives

By applying self monitoring of glucose, patients with Diabetes Mellitus type two (DM2) may cope more independently with their disease. Self monitoring can aid in diabetes control by giving the patient the ability to make appropriate day-to-day treatment choices in diet and physical activity as well as in medication. Furthermore, it will improve a patient's recognition of hypoglycaemia or severe hyperglycaemia, and enhance patient empowerment regarding the effects of lifestyle and medication on glycaemic control and thereby provide a better perceived quality of life.

Please note that as of 26/10/2009 this trial was updated. All updates can be found under the relevant field with the above update date. The overall trial end date has been extended from 01 /07/2009.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The ethics board of the VU Medical Centre, 22/11/2007

Study design

Randomised active-controlled parallel-group trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Diabetes Mellitus type two (DM2)

Interventions

A stratified, randomised six-arm clinical trial among DM2 patients with an Hb1Ac of 7.0% or above who are not using insulin. Eligible and consenting subjects will be randomly assigned to the intervention groups Self Monitoring of Blood Glucose (SMBG) or Self Monitoring of Urine Glucose (SMUG), or to the control group.

Before randomisation the patients will be stratified according to treatment (i.e. using Sulphonylureas [SU] or not [Non-SU]). The SMBG and SMUG will be an integral part of a wider educational strategy; the intervention groups and the control group will receive a standardised treatment program to change their diet and lifestyle.

In addition, patients in the SMBG group will be educated to use the SMBG-device and patients in the SMUG-group will be educated to use the urine tests. They will learn to know and understand the ranges of test results and what steps to take in response to a high or low, or positive or negative reading.

The intervention groups will perform self-monitoring according to standard testing frequency instructions during one year.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Problem Areas In Diabetes scale (PAID) assessed at baseline and at 6 and 12 months after inclusion
- 2. Glycaemic control measured by glycated haemoglobin concentration (HbA1c-level) at baseline and at 6 and 12 months after inclusion
- 3. Cost-effectiveness assessed using cost-diaries and the European Quality of Life (EuroQoL) questionnaire

Secondary outcome measures

- 1. Frequency and severity of hypoglycaemia
- 2. Change in well-being: 12-item Well Being Questionnaire (WBQ-12)
- 3. Patient satisfaction: Diabetes Treatment Satisfaction Questionnaire (DTSQ)
- 4. Changes in lifestyle factors:
- a. diet behaviour (Dutch Eating Behaviour Questionnaire [DEBQ])
- b. physical activity (Short Questionnaire to Assess Health enhancing physical activity [SQUASH])
- 5. Changes in medication use
- 6. Compliance
- 7. Medical care utilisation

All secondary outcomes will be assessed at baseline, 6 and 12 months after inclusion.

Overall study start date

01/07/2007

Completion date

01/11/2010

Eligibility

Key inclusion criteria

- 1. All patients are participants of the Diabetes Care System West-Friesland
- 2. Patients with type two diabetes with HbA1c levels of 7.0% or above who are not using insulin
- 3. Younger than 76 years
- 4. Known disease duration of over one year
- 5. Not used self monitoring of glucose in the previous year

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

600

Key exclusion criteria

- 1. Severe complications of diabetes
- 2. Pregnant women
- 3. Unable to carry out self monitoring of glucose
- 4. Unable to fill in questionnaires/diaries

Date of first enrolment

01/07/2007

Date of final enrolment

01/11/2009

Locations

Countries of recruitment

Netherlands

Study participating centre VU Medical Centre Amsterdam

Amsterdam Netherlands 1081 BT

Sponsor information

Organisation

Vrije University Medical Centre (VUMC) (The Netherlands)

Sponsor details

EMGO-Institute Van der Boechorststraat 7 Amsterdam Netherlands 1081 BT +31 (0)20 444 8180 emgo@vumc.nl

Sponsor type

Hospital/treatment centre

Website

http://www.vumc.nl/english/

ROR

https://ror.org/00q6h8f30

Funder(s)

Funder type

Research organisation

Funder Name

European Foundation for the Study of Diabetes (EFSD) (Germany)

Alternative Name(s)

The European Association for the Study of Diabetes, EFSD

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Germany

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?
Protocol article	protocol	27/04/2009		Yes	No
Results article	results	01/04/2016		Yes	No
Results article	results	01/04/2016		Yes	No