

# Evaluation of the necessary frequency of blood glucose self-monitoring in type 2 diabetic patients. A prospective, controlled, randomised, multicenter study.

**Submission date**

05/09/2005

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

28/10/2005

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

09/09/2008

**Condition category**

Nutritional, Metabolic, Endocrine

☐ 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

## Study objectives

To evaluate the impact of the frequency of blood glucose self-monitoring on glycaemic control (HbA1c and occurrence of hypoglycaemia) of type 2 diabetic patients. Currently there are no general recommendations on the frequency of self blood glucose monitoring in type 2 diabetics treated with a fixed insulin regime or oral antidiabetic medication. The study intends to compare over a follow-up period of 6 month patients with a high frequency of self-monitoring with those with a low frequency. This comparison is done separately for two groups of patients:

1. Treated with a fixed insulin regime
2. Treated with oral antidiabetic drugs only

Satisfaction with the recommended treatment is a secondary endpoint of the study.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Type 2 diabetes mellitus

## Interventions

Blood glucose monitoring

1. Patients on insulin mixture:

1.1 Maximum recommendation: every day fasting, every second day before dinner, additional

once a profile

1.2 Minimum recommendation: once a week a fasting blood glucose

2. Patients who get an oral antidiabetic:

2.1 Maximum recommendation: every second day a fasting blood glucose, once a week a blood sugar check before dinner

2.2 Minimum recommendation: one fasting blood glucose per week

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

HbA1c six months after start of the study

### **Secondary outcome measures**

1. Hypoglycaemia with necessary outside help
2. Hyperosmolar coma
3. Quality of life
4. Compliance
5. HbA1c after 12 months

### **Overall study start date**

01/12/2003

### **Completion date**

01/10/2006

## **Eligibility**

### **Key inclusion criteria**

1. Patients treated with a fixed dose of mixture insulin twice a day
2. Patients who are treated with one or more oral antidiabetic drugs
3. From 35 to 80 years
4. Informed consent
5. Type 2 diabetic patients

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

400 (100 in each group)

**Key exclusion criteria**

1. Treatment with multiple insulin injections (more than 2/day)
2. Type 1 diabetic patients
3. Advanced renal insufficiency (known creatinine >2.5 mg/dl)
4. >2 hypoglycaemia with necessary outside help within the last three months
5. Hypoglycaemic shock/hyperosmolaric coma within the last three months
6. Pregnancy
7. Severe impaired vision
8. Communication problems
9. Home care/nursing service

**Date of first enrolment**

01/12/2003

**Date of final enrolment**

01/10/2006

**Locations****Countries of recruitment**

Germany

**Study participating centre**

Deutsches Diabetes Zentrum an der Heinrich-Heine-Universität

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**Sponsor information****Organisation**

Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) (Germany)

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**Sponsor type**

Government

ROR

<https://ror.org/04pz7b180>

## Funder(s)

### Funder type

Government

### Funder Name

Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) - Germany - 01GL0303

## 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:	28/08/2008		Yes	No