

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	<input type="checkbox"/> Prospectively registered
Registration date 28/10/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/09/2008	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

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

Study type(s)

Treatment

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(s)

HbA1c six months after start of the study

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Duesseldorf

Germany

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Sponsor information

Organisation

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

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

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:	28/08/2008		Yes	No