ISRCTN79164268 https://doi.org/10.1186/ISRCTN79164268

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

Registration date
28/10/2005

Overall study status
Completed

Last Edited
09/09/2008

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Werner A. Scherbaum

Contact details
Deutsches Diabetes Zentrum an der Heinrich-Heine-Universität
Auf´m Hennekamp 65
Duesseldorf
Germany
40225
+49 (0)2113382-200
scherbaum@ddz.uni-duesseldorf.de

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
Duesseldorf
Germany
40225

Sponsor information

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

Sponsor details
Südstrasse 125
Bonn
Germany
53175
+49 (0)2283821202
cornelia.bormann@dlr.de

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?
Results article	Results:	28/08/2008		Yes	No