Evaluating glucose control before, during and after haemodialysis in patients with diabetes who are using insulin.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20090

Source
Nationaal Trial Register

Brief title
NA

Health condition

diabetes mellitus
haemodialysis
continuous glucose monitoring

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: This is mainly a self financing research project and funding is therefore provided by the sponsor (i.e. University Medical Center Groningen). In addition, CGM devices are provided free of charge and without restrictions by Abbott Nederland.

Intervention

Outcome measures

Primary outcome

Mean glucose concentration and area-under-the-curve (AUC) glucose during 24-hour periods, on days with and without haemodialysis.

Secondary outcome

1. Frequency of glucose < 3.5 mmol/L, < 3.0 mmol/L and < 2.5 mmol/L;

2. Frequency and severity of self-reported symptomatic hypoglycaemia;

3. Correlation between day-to-day variations in physical activity and glucose levels;

4. Correlation between day-to-day variations in food intake and glucose levels;

5. Elimination rate of insulin and/or glucose during haemodialysis.

Study description

Background summary

Rationale:

Glucose control in diabetic patients with end stage renal disease might be influenced by treatment with haemodialysis, but data on this subject are limited. Haemodialysis could affect glucose control through several mechanisms. It has been suggested that insulin is eliminated directly by the haemodialysis procedure itself. In addition, glucose control during haemodialysis could also be influenced by indirect mechanisms such as changes in food intake and physical activity.
Objective: The main objective is to compare glucose profiles recorded by continuous glucose monitoring (CGM) on days with and without haemodialysis in a group of insulin treated diabetic patients. Secondary objectives are to evaluate the relationship between food intake or physical activity and glucose profiles on days with and without haemodialysis and to examine the pharmacokinetics of insulin during haemodialysis.

Study design:

Short term invasive observational multicenter study.

Study population:

Adult patients (age=/> 18 years) with insulin treated diabetes undergoing regular haemodialysis treatment (n=20).

Main study parameters/endpoints:

Mean glucose concentration and area-under-the-curve (AUC) of glucose during 24-hour periods, frequency and severity of hypoglycaemic episodes, on days with and without haemodialysis.

Methods:

Glucose measurement by continuous glucose monitoring during 5 days. Food intake and hypoglycaemic episodes are recorded by the patients in a structured diary. Physical activity is monitored by means of a pedometer, except in those patients who are immobilised (e.g. leg amputation, paralysis). A subgroup of 10 diabetic patients also participates in a pharmacokinetics study. In these patients, blood samples for determination of glucose and insulin will be drawn before, during (at one hour intervals) and directly after one haemodialysis session simultaneously from the arterial and venous side of the haemodialysis unit. Dialysate will be sampled simultaneously for glucose measurement.

Study objective

Glucose control in diabetic patients with end stage renal disease might be influenced by treatment with haemodialysis, but data on this subject are limited. Haemodialysis could affect glucose control through several mechanisms. It has been suggested that insulin is eliminated directly by the haemodialysis procedure itself. In addition, glucose control during haemodialysis could also be influenced by indirect mechanisms such as changes in food intake and physical activity.
The main objective of this study is to compare glucose profiles recorded by continuous glucose monitoring (CGM) on days with and without haemodialysis in a group of insulin treated diabetic patients. Secondary objectives are to evaluate the relationship between food intake or physical activity and glucose profiles on days with and without haemodialysis and to examine the pharmacokinetics of insulin during haemodialysis.

Study design

The observation period of each participant is 5 days, during which CGM takes place.

Intervention

Continuous glucose monitoring (CGM) will be performed during 5 days in each participant. Participants receive regular daytime haemodialysis 3 times a week and CGM is started at the beginning of the first session of the week.

Contacts

Public
Department of Endocrinology
University Medical Center Groningen
M.N. Kerstens
Groningen
The Netherlands
+31 (0)50 3616161/3518
Scientific
Department of Endocrinology
University Medical Center Groningen
M.N. Kerstens
Groningen
The Netherlands
+31 (0)50 3616161/3518

Eligibility criteria

Inclusion criteria

1. Insulin treated diabetes (type 1 or type 2) on haemodialysis;

2. Age =/> 18 years;

3. Male or female.

Exclusion criteria

1. Secondary form of diabetes;

2. Use of oral hypoglycaemic drugs;

3. Use of oral/parental glucocorticoids;

4. Inability to understand written and oral instructions in Dutch and to adhere to study

protocol.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-11-2010
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-01-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39344
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3616
NTR-old	NTR3782
CCMO	NL32332.042.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39344

Study results

Summary results

(1) Abe M, Kaizu K, Matsumoto K. Evaluation of the hemodialysis-induced changes in plasma glucose and insulin concentrations in diabetic patients: comparison between the hemodialysis and non-hemodialysis days. Ther Apher Dial 11, 288-295. 2007.
(2) Kazempour-Ardebili S, Lecamwasam VL, Dassanyake T et al. Assessing glycemic control in maintenance hemodialysis patients with type 2 diabetes. Diabetes Care 2009; 32(7):1137-1142.
(3) Riveline JP, Teynie J, Belmouaz S et al. Glycaemic control in type 2 diabetic patients on chronic haemodialysis: use of a continuous glucose monitoring system. Nephrol Dial Transplant 2009; 24(9):2866-2871.