

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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20090

Bron

NTR

Verkorte titel

NA

Aandoening

diabetes mellitus

haemodialysis

continuous glucose monitoring

Ondersteuning

Primaire sponsor: University Medical Center Groningen

Overige ondersteuning: 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.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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= $\geq$ 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Insulin treated diabetes (type 1 or type 2) on haemodialysis;
2. Age $\geq$ 18 years;
3. Male or female.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	23-11-2010
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	06-01-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39344
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

- (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, Lecomwasam 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.