Randomized, controlled, multinational, multi-center, clinical trial to examine whether HbA1c can improve in type 1 diabetes patients who continuously use the Paradigm® REAL-Time system with alarm function as compared to patients on multiple injection therapy receiving one six-day period of continuous glucose monitoring - without alarm function (Guardian® REAL-Time Clinical).

Gepubliceerd: 24-01-2007 Laatst bijgewerkt: 18-08-2022

HbA1c can improve in type 1 diabetes patients who continuously use the Paradigm® REAL-Time system.

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24667

Bron
NTR

Verkorte titel
The Eurythmics Trial

Aandoening

Type I Diabetes

Ondersteuning

Primaire sponsor: dr. J.H. de Vries
Academic Medical Centre
Department of Internal Medicine
Overige ondersteuning: Medtronic B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

HbA1c.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

HbA1c can improve in type 1 diabetes patients who continuously use the Paradigm® REAL-Time system.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Using the Paradigm® REAL-Time device, consisting of a continuous subcutaneous glucose sensor, equipped with an alarm function for upcoming hypo- and hyperglycemia, an insulin pump and a Bolus Wizard® calculator

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients have been diagnosed with type 1 diabetes at least 12 months prior to study entry;

2. Patients are between 18 and 65 years of age, inclusive;

3. Patients are on multiple injection treatment, defined as a basal insulin analogue qd or bid and a rapid-acting insulin analogue used with every meal OR
Patients are on conventional MIT in whom previous treatment with long- and rapid-acting insulin has failed;

4. Patients are on multiple injection treatment at least 3 months prior to inclusion;

5. Patients have a baseline HbA1c ¡Ý 8.2%

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patient has hearing problems or impaired vision that might hinder recognition of the sensor alarm or screen alarms, respectively;

2. Alcohol or drug abuse other than nicotine;

3. Abdominal abnormalities, like lipodystrophia that might hinder either glucose measurement by the sensor or the continuous subcutaneous insulin infusion;

4. Current pharmaceutical treatment for any psychiatric disorder other than depression;

5. Treatment with CSII in the last six months prior to entry in the study;

6. Patients suffering from Cancer, Heart Failure, kidney disease (creatinin > 150 micromol/l) and other chronic debilitating conditions;

7. Patient is unwilling or unable to comply with the provisions of the protocol;

8. Patient has scheduled a vacation which will occur between Visit 1 and Visit 2;

9. Patient has planned trips when he/she will be out of telephone reach from the study medical care for >5 days or to a place where he/she cannot comply with study procedures;

10. Being pregnant, or the wish to become pregnant during the trial;

11. Patient is participating in another device or drug study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2007
Aantal proefpersonen:	104
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL849
NTR-old	NTR863
Ander register	: N/A
ISRCTN	ISRCTN22472013

Resultaten

Samenvatting resultaten
N/A