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).

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24667

Source
Nationaal Trial Register

Brief title
The Eurythmics Trial

Health condition

Type I Diabetes

Sponsors and support

Primary sponsor: dr. J.H. de Vries
Academic Medical Centre
Department of Internal Medicine
Source(s) of monetary or material Support: Medtronic B.V.

Intervention

Outcome measures

Primary outcome

HbA1c.

Secondary outcome

1. Hypoglycemie;

2. Hyperglycemie;

3. Quality of Life;

4. Contact tijd met onderzoeker.

Study description

Background summary

N/A

Study objective

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

Study design

N/A

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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%

Exclusion criteria

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.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2007
Enrollment:	104
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results

Summary results
N/A