# 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).

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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**
Nationaal Trial Register

**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

## Publiek

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## Wetenschappelijk

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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