ISRCTN22472013 https://doi.org/10.1186/ISRCTN22472013

Randomised, controlled, multinational, multicentre, clinical trial to examine whether HbA1c can improve in type one 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)

Submission date
08/02/2007

Registration date
08/02/2007

Last Edited
21/12/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
The Eurythmics Trial

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics board (Medisch Ethische Commissie) on the 18th January 2007 (ref: MEC 06/302, ref of approval: 06-302 07.17.0102).

Study design
Randomised, controlled, parallel group multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Diabetes Mellitus Type one (DM type one)

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

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
HbA1c levels.

Secondary outcome measures
1. Hypoglycaemic
2. Hyperglycaemic
3. Quality of life
4. Time spent with the researcher during a visit (Contact tijd met onderzoeker)

Overall study start date
01/02/2007

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Patients have been diagnosed with type one diabetes at least 12 months prior to study entry
2. Patients are between 18 and 65 years of age, inclusive
3. Patients are:
a. on Multiple Injection Treatment (MIT), defined as a basal insulin analogue once or twice a day and a rapid-acting insulin analogue used with every meal, or
b. on conventional MIT in whom previous treatment with long- and rapid-acting insulin has failed
4. Patients are on multiple injection treatment at least three months prior to inclusion
5. Patients have a baseline HbA1c of more than or equal to 8.2%

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
104

Key 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 Continuous Subcutaneous Insulin Infusion (CSII) in the last six months prior to entry in the study
6. Patients suffering from cancer, heart failure, kidney disease (creatinine more than 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 one and visit two
9. Patient has planned trips when he/she will be out of telephone reach from the study medical care for more than five 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

Date of first enrolment
01/02/2007

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
Department of Internal Medicine
P.O. Box 22660
Amsterdam
Netherlands
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Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
Medtronic B.V. (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2011		Yes	No