

# Paediatric onset study to assess the efficacy of insulin pump therapy using the MiniMed Paradigm® REAL-Time system during the first year of diabetes in children and adolescents with type 1 diabetes

**Submission date**

06/07/2008

**Recruitment status**

No longer recruiting

Prospectively registered

Protocol

**Registration date**

31/07/2008

**Overall study status**

Completed

Statistical analysis plan

Results

**Last Edited**

02/05/2013

**Condition category**

Nutritional, Metabolic, Endocrine

Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Thomas Danne

**Contact details**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

MHH 4432

## **Study information**

**Scientific Title**

**Acronym**

ONSET

**Study objectives**

Paediatric patients using the MiniMed Paradigm® REAL-Time system providing a combination of insulin pump and REAL-Time continuous glucose monitoring from the onset of type 1 diabetes have a better glycaemic control after 12 months of type 1 diabetes compared to those using the MiniMed Paradigm® insulin pump combined to conventional self-monitoring blood glucose (SMBG) finger-sticks.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval received from the Ethics Committee of the Medizinische Hochschule Hannover on the 14th December 2006.

**Study design**

Prospective, international multi-centre open randomised clinical trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Type 1 diabetes mellitus

**Interventions**

Patients will be randomised into two groups:

Group A: MiniMed Paradigm® REAL-Time insulin pump system with continuous glucose monitoring

Group B: MiniMed Paradigm® 515/715 insulin pump with conventional SMBG measurements. Patients of Group B will be required to wear the Guardian REAL-Time Clinical (blinded continuous glucose monitor) for 6 days prior to two visits.

Each subject will participate for 15 months, which includes 12 months treatment and 3 months follow-up. In total, there will be six study visits at the local site. Main timepoints of assessment are at baseline and 12 months thereafter. During study, patients will regularly attend the outpatient clinic according to local standard care. Analysis of HbA1c, diabetes-associated autoantibodies and fasting C-peptide will be performed during study.

As of 16/10/2009 this record was updated to include the correct sponsor details; at the time of registration, the funder was also indicated to be the sponsor.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

HbA1c (central determination with HPLC) after 12 months of treatment, measured at baseline, 6 weeks, and 6, 12, 15 and 24 months.

### **Secondary outcome measures**

1. Dose of insulin per day, percentages of basal and bolus insulin dose as calculated from the pump downloads using the CareLink software, measured at 6 weeks and 6, 12, 15 and 24 months
2. Average number of daily boluses as calculated from the pump downloads using the CareLink software, measured at 6 weeks and 6, 12, 15 and 24 months
3. Frequency of sensor use, measured at 6 weeks and 6, 12, 15 and 24 months (group A only)
4. Frequency of daily SMBG measurements, measured at baseline, 6 weeks and 6, 12, 15 and 24 months
5. Stimulated C-peptide, measured at baseline, 12 and 24 months
6. Height and Ht SDS, weight and Wt SDS, BMI and BMI SDS, measured at baseline, 6 weeks and 6, 12, 15 and 24 months
7. Glucose average and variation during 24h as documented by Paradigm REAL-Time and Guardian REAL-Time Clinical (blinded to glucose values) in the control group
8. Occurrence of hypoglycaemia below 70 mg/dl (3.9 mmol/l) during 24 hour expressed as Area under the Curve (AUC) below 70 mg/dl (3.9 mmol/l), measured at 6 weeks and 6, 12, 15 and 24 months
9. Occurrence of hyperglycaemia above 200 mg/dl (11.1 mmol/l) during 24 hours expressed as Area Under the Curve (AUC) above 200 mg/dl (11.1 mmol/l), measured at 6 weeks and 6, 12, 15 and 24 months
10. Serious adverse events (severe hypoglycaemia/DKA), measured at 6 weeks and 6, 12, 15 and 24 months
11. Treatment/device complications reported by patients/parents
12. Patient's QoL outcome (DISABKIDS for children aged 8 - 16 years), measured at -1 day and 6, 12 and 24 months
13. Care giver's QoL outcome (DISABKIDS), measured at -1 day and 6, 12 and 24 months

14. Care giver's psychological well-being (WHO 5 questionnaire), measured at -1 day and 6, 12 and 24 months

15. Socioeconomic burden for families (SBQ), measured at -1 day and 6, 12 and 24 months

**Overall study start date**

01/12/2006

**Completion date**

31/08/2009

## **Eligibility**

**Key inclusion criteria**

1. Provided written informed consent
2. Aged between 1 (inclusive) and 17 (exclusive) years (either sex) and diagnosed with type 1 diabetes at latest 4 weeks prior to study entry
3. Patients must be willing to use the MiniMed Paradigm® REAL-Time system or MiniMed Paradigm® 515/715 insulin pump combined to conventional SMBG finger sticks for 12 months
4. Patients must be able and willing to perform at least two SMBG finger sticks daily
5. Patients are willing to undergo all study procedures
6. Training on how to adapt their insulin dose to their meals and awareness of how to calculate and apply corrective insulin boluses as well as of the influence of physical activity and their life style factors on their metabolic control
7. Patients are willing to participate to the MiniMed Paradigm® REAL-Time system (Group A) and to the MiniMed Paradigm® 515/715 plus the Guardian REAL-Time Clinical (Group B)

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

1 Years

**Upper age limit**

17 Years

**Sex**

Both

**Target number of participants**

160 patients will be recruited

**Key exclusion criteria**

1. Hearing or vision impairment so that alarms cannot be recognised
2. Patient does not have reliable support person or is unwilling to comply with the provisions of the protocol
3. Mental incapacity
4. Language barriers precluding adequate understanding or cooperation

5. Patients suffering from severe chronic disease or genetic disorder other than type 1 diabetes (i.e. Down syndrome, etc.)
6. Pregnancy
7. Eating disorders
8. Alcohol or drug abuse other than nicotine
9. Patients participating in other device or drug related studies
10. Patients disclaimer of study participation

**Date of first enrolment**

01/12/2006

**Date of final enrolment**

31/08/2009

## **Locations**

**Countries of recruitment**

Austria

France

Germany

Poland

Sweden

United Kingdom

**Study participating centre**

**Kinderkrankenhaus auf der Bult**

Hannover

Germany

30173

## **Sponsor information**

**Organisation**

Hannover Childrens Hospital (Hannoversche Kinderheilstalt) (Germany)

**Sponsor details**

Janusz-Korczak-Allee 12

Hannover

Germany

30173

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.hka.de/start.html>

**ROR**

<https://ror.org/024f43q37>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Medtronic International Trading Sarl (Switzerland) - donating equipment

## 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?
<a href="#">Results article</a>	results	01/12/2010		Yes	No
<a href="#">Results article</a>	results	01/11/2012		Yes	No