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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

Registration date
31/07/2008

Overall study status
Completed

Last Edited
02/05/2013

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

Protocol serial number
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.

Primary study design
Interventional

Study design
Prospective, international multi-centre open randomised clinical trial

Study type(s)
Treatment

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 Years

Upper age limit
17 Years

Sex
All

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
United Kingdom

Austria

France

Germany

Poland

Sweden

Study participating centre
Kinderkrankenhaus auf der Bult
Hannover
Germany
30173

Sponsor information

Organisation
Hannover Childrens Hospital (Hannoversche Kinderheilanstalt) (Germany)

ROR
https://ror.org/024f43q37

Funder(s)

Funder type
Industry

Funder Name
Medtronic International Trading Sarl (Switzerland) - donating equipment

Results and Publications

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	01/12/2010		Yes	No
Results article	results	01/11/2012		Yes	No