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SWITCH - Sensing With Insulin pump Therapy to Control HbA1c

Submission date	Recruitment status
05/12/2007	No longer recruiting
Registration date	**Overall study status**
23/01/2008	Completed
Last Edited	**Condition category**
28/02/2019	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
NCT00598663

Secondary identifying numbers
EUR03

Study information

Scientific Title
Randomised, cross-over, controlled, multi-centric study to assess whether type 1 diabetic patients in sub-optimal glycaemic control can improve using the continuous glucose values of the MiniMed Paradigm REAL-Time Insulin Pump system versus the MiniMed Paradigm Insulin Pump

Acronym
SWITCH

Study objectives
Null hypothesis: There is a 0% reduction in HbA1c from baseline compared to control group, after 6 months of treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ljubljana Clinical Centre, Institute for Neurophysiology (Intitut za klinicno nevrofiziologijo, Klinicni center Ljubljana, Zaloka 7,1525 Ljubljana) (Slovenia) in December 2007.

Study design
Randomised controlled two-arm cross-over multicentre trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Type 1 diabetes mellitus

Interventions
Treatment: Insulin pump with continuous glucose sensing
Control: Insulin pump with self-monitoring blood glucose

There are 2 x arms of 6 months (crossover) and a washout period between the arms of 4 months (i.e. 6 months of first treatment regimen followed by a 4-month washout, then crossed over to the other treatment for 6 months).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
HbA1c, measured at baseline, midway and at the end of each arm.

Secondary outcome measures
1. Change in glycaemic variability
2. Change in occurrence of hypoglycaemia, measured throughout the study duration (approximately 16 months per patient)
3. Time spent in euglycaemia
4. Change in postprandial glycaemia
5. Quality of life (paediatrics) and treatment satisfaction (adults), assessed by the paediatric quality of life inventory (PedsQL) and the diabetes treatment satisfaction questionnaires (DTSQs), respectively, at baseline and end of each arm
6. Severe hypoglycaemia or diabetic ketoacidosis (DKA) events, measured throughout the study duration (approximately 16 months per patient)

Overall study start date
01/01/2008

Completion date
01/07/2010

Eligibility

Key inclusion criteria
1. Type 1 diabetes mellitus diagnosed for at least 12 months prior to signature of informed consent
2. Patients aged 6 years to 70 years old, both male and female
3. Sub-optimal glycaemic control (7.5% less than HbA1c less than 9.5%)
4. Patient treated by continuous subcutaneous insulin infusion (CSII) for at least 6 months prior signature of informed consent
5. Patient treated within the practice of the investigator's centre at least 6 months prior to signature of informed consent
6. Patient has no preliminary experience with the sensor function of the Paradigm Real-Time (PRT)® or the Guardian® REAL-Time for the 4 months prior signature of informed consent

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Existing pregnancy or intention to conceive (as assessed by investigator)
2. Hearing or vision impairment so that glucose display and alarms cannot be recognised
3. Three or more incidents in the last 12 months of severe hypoglycaemia with documented blood glucose (BG) below 50 mg/dL (if possible), resulting in unconsciousness, hospitalisation or third party assistance, where recovery follows treatment with glucose or glucagon or similar
4. History of hypoglycaemic unawareness as assessed by the investigator
5. Alcohol or drug abuse, other than nicotine
6. Documented cutaneous allergy or disease (allergy to sensor or components of the sensor, psoriasis, staphylococcus, exanthema, etc.)
7. Any documented concomitant chronic disease known to affect diabetes control (e.g., altered renal function, active cancer undergoing treatment, Crohn's disease, ulcerative colitis, Addison's disease) or any concomitant pharmacological treatment that might modify glycaemic values (e. g., chronic corticosteroid therapy), eating disorders and morbid obesity (defined as adults: body mass index (BMI) greater than 35 and children BMI greater than 2 s.d. for age) as assessed by the investigator
8. Any other medical, social or psychological condition that, in the investigator's opinion, makes the patient unable to comply with the study protocol and all study procedures
9. For paediatric subjects: does not have a reliable support person
10. Plans to travel for extended periods (3+ weeks) where the devices cannot be supplied or replaced and/or medical support is limited (e.g., exotic countries, remote places)
11. Participation in another clinical study, ongoing or completed less than 3 months prior to signature of patient informed consent

Date of first enrolment
01/01/2008

Date of final enrolment
01/07/2010

Locations

Countries of recruitment
Austria

Denmark

Italy

Luxembourg

Netherlands

Slovenia

Spain

Study participating centre
University Children's Hospital
Ljubljana
Slovenia
SI-1525

Sponsor information

Organisation
Medtronic International Trading Sarl (Switzerland)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Medtronic International Trading Sarl (Switzerland)

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	01/12/2012	28/02/2019	Yes	No