

SWITCH - Sensing With Insulin pump Therapy to Control HbA1c

Submission date
05/12/2007

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
23/01/2008

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
28/02/2019

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
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00598663

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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)

ROR

<https://ror.org/04pf17v09>

Funder(s)

Funder type

Industry

Funder Name

Medtronic International Trading Sarl (Switzerland)

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