SWITCH - Sensing With Insulin pump Therapy to Control HbA1c

Submission date	Recruitment status No longer recruiting	Prospectively registered		
05/12/2007		☐ Protocol		
Registration date 23/01/2008	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
28/02/2019	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Tadej Battelino

Contact details

University Children's Hospital Vrazov trg 1 Ljubljana Slovenia SI-1525

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)

Sponsor details

Route Molliau, 31 Tolochenaz Switzerland 1131 +41 (0)21 802 7614 hannah.gough@medtronic.com

Sponsor type

Industry

Website

http://www.medtronic.com/

ROR

https://ror.org/04pf17v09

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 summaryNot 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