Standardized Evaluation of Subcutaneous Glucose Monitoring Systems Under Routine Environmental Conditions

This study has been completed.

Sponsor:
Medical University of Graz
Information provided by (Responsible Party):
Medical University of Graz
ClinicalTrials.gov Identifier:
NCT02614768

First received: November 24, 2015
Last updated: March 2, 2016
Last verified: March 2016

Purpose

The purpose of this study is to assess accuracy and reliability of the SPIDIMAN CGM sensor system with regard to values as measured by Super GL and compare these results with similar evaluations of the Medtronic MiniMed 640G system, the Abbott FreeStyle Libre Flash Sensor and the DexCom G4 Platinum Sensor in patients with type 1 Diabetes.

Condition	Intervention
Diabetes Mellitus, Type 1	Device: Glucose Sensor

Study Type: Interventional

Study Design: Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Basic Science

Official Title: Standardized Evaluation of Subcutaneous Glucose Monitoring Systems Under Routine Environmental Conditions

Resource links provided by NLM:

Genetics Home Reference related topics: type 1 diabetes

MedlinePlus related topics: Diabetes Type 1

Drug Information available for: Dextrose

U.S. FDA Resources

Further study details as provided by Medical University of Graz:

Primary Outcome Measures:

- Percentage of test-to-reference measurement pairs with an Absolute Relative Difference (ARD) ≤15%. [Time Frame: 36 hours]

Enrollment: 12

Study Start Date: July 2015

Study Completion Date: September 2015

Primary Completion Date: August 2015 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Glucose Sensor Continuous subcutaneous glucose monitoring using four different CGM systems in parallel will be performed throughout the study. Insulin therapy will be performed by the subjects themselves, as under daily life conditions. For the hypoglycaemia experiment an increased insulin bolus will be administered with meals (180% of the subject's calculated mealtime dose).	Device: Glucose Sensor The investigational intervention is CGM monitoring using four different CGM systems. Three of the four CGM devices which are used will be CGM systems which have received CE certification (Dexcom G4 Platinum, Medtronic MiniMed 640G system, Abbott FreeStyle Libre Flash). The SPIDIMAN sensor will be used for the first time in human subjects, does not yet have received CE certification and will be given an identifying

	label in addition to being labelled "for investigative use only".

Detailed Description:

The study is a single-center open-label study in patients with type 1 diabetes treated with continuous subcutaneous insulin infusion (CSII) or multiple daily injections (MDI) therapy. The study will include a total of 12 subjects.

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Informed consent obtained after being advised of the nature of the study
- Male or female aged ≥18 years
- Type 1 diabetes for at least 6 months according to the WHO definition
- Treatment with multiple daily injections (MDI) or continuous subcutaneous insulin infusion (CSII) for at least 3 months
- Body Mass Index (BMI) < 35 kg/m²
- Willing and able to wear 5 CGM devices for the duration of the study and undergo all study procedures.
- HbA1c ≤ 86 mmol/mol

Exclusion Criteria:

- Any disease or condition which the investigator or treating physician feels would interfere with the trial or the safety of the subject
- Female of childbearing potential who is pregnant, breast-feeding or intend to become pregnant or is not using adequate contraceptive methods
- Any mental condition rendering the subject incapable of giving his consent
- Subject is using a medication that significantly impacts glucose metabolism (oral steroids) except if stable for at least the last three months and expected to remain stable for the study duration
- Subject may not use acetaminophen (paracetamol) while participating in the study
- Has severe medical or psychological condition(s) or chronic conditions/infections that in the opinion of the Investigator would compromise the subject's safety or successful participation in the study.

- Subject is actively enrolled in another clinical trial
- Known adrenal gland problem, pancreatic tumour, or insulinoma
- Inability of the subject to comply with all study procedures
- Inability of the subject to understand the patient information.
- Subject donated blood in the last 3 months

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02614768

Sponsors and Collaborators

Medical University of Graz

Investigators

Principal Investigator: Julia Mader, Prof. Dr. Medical University of Graz

More Information

Responsible Party:	Medical University of Graz
ClinicalTrials.gov Identifier:	NCT02614768 History of Changes
Other Study ID Numbers:	SPIDIMAN_01
Study First Received:	November 24, 2015
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Keywords provided by Medical University of Graz:

Glucose Monitoring System

Additional relevant MeSH terms:

Diabetes Mellitus
Diabetes Mellitus, Type 1
Glucose Metabolism Disorders
Metabolic Diseases
Endocrine System Diseases
Autoimmune Diseases
Immune System Diseases

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