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User Evaluation of the DexCom™ SEVEN.2 Continuous Glucose Monitoring System

Submission date	Recruitment status	[ ] Prospectively registered
19/05/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/06/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/06/2009	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Thomas Danne

Contact details
Janusz-Korczak-Allee 12
Hannover
Germany
30173

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol Nr. 5181

Study information

Scientific Title

User Evaluation of the DexCom™ SEVEN.2 Continuous Glucose Monitoring System: a single-centre prospective non-randomised masked/un-masked intervention study

Study objectives
The study intends to evaluate user experience with the DexCom™ SEVEN.2 Continuous Glucose Monitoring System in the home environment and the effect of its use on glycaemic control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Hannover Medical School approved on the 28th November 2008

Study design
Single-centre prospective non-randomised masked/un-masked intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

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

Interventions
During baseline Phase 1 (duration 21 days), subjects will be masked to the display of the DexCom™ SEVEN.2 continuous glucose readings. Subjects will calibrate the DexCom™ SEVEN.2 Receiver using standard fingerstick blood glucose testing with test strips. Subjects will manage their diabetes based upon the blood glucose measurements using their established regimen prescribed by their healthcare professional prior to study enrolment.

At the end of the Phase 1, subjects will return to the clinic to have their DexCom™ SEVEN.2 systems set to display continuous glucose readings and enable low and high glucose alarms. Subjects will continue for the rest of the study using the DexCom™ SEVEN.2 system as an adjunctive device to guide glucose management according to its intended use and warnings given in the User's Guide along with the advice of the study Investigator.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To evaluate improvement in glycaemic variability in children, adolescents, and young adults, particularly in the reduction of the number of hypo- and hyper-glycaemic events, reduction of time spent outside of euglycemia glucose range, and reduction of glucose variability (standard deviation) through use of the DexCom™ SEVEN.2 Continuous Glucose Monitoring System, between masked and un-masked period.

Secondary outcome measures
To evaluate user experience with the DexCom™ SEVEN.2 Continuous Glucose Monitoring System. The HbA1C level will also be evaluated; the unmasked baseline phase A1C will serve as a self-control for the subjects.

Overall study start date
15/12/2008

Completion date
15/04/2009

Eligibility

Key inclusion criteria
1. Documented type 1 diabetes mellitus diagnosis at least 1 year prior to enrolment
2. Recommended to perform daily self-monitoring blood glucose testing
3. Performing multiple daily insulin injections, or has been on an insulin pump, for at least 6 months prior to enrolment
4. Less than 24 years of age, either sex
5. Willing and capable of following the protocol and instructions provided by the investigator
6. Available for the entire study duration of 63 days and for follow up on scheduled study visit days
7. Provided written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Target enrolment: 55 patients with the aim of 50 completion

Key exclusion criteria
1. Subject has had an episode of severe hypoglycaemia in past four weeks prior to enrolment
2. Allergy to medical grade adhesives
3. Any medical condition or medication, which in the investigators opinion, may compromise

patient safety
4. Participation in any other study which may affect glucose measurements or glucose management
5. Known, suspected or planning pregnancy during study participation

Date of first enrolment
15/12/2008

Date of final enrolment
15/04/2009

Locations

Countries of recruitment
Germany

Study participating centre
Janusz-Korczak-Allee 12
Hannover
Germany
30173

Sponsor information

Organisation
DexCom Inc. (USA)

Sponsor details
6340 Sequence Drive
San Diego
United States of America
92121

Sponsor type
Industry

Website
http://www.dexcom.com

ROR
https://ror.org/03ra42c27

Funder(s)

Funder type
Industry

Funder Name
DexCom Inc. (USA)

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