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

Submission date
19/05/2009

Recruitment status
No longer recruiting

Registration date
29/06/2009

Overall study status
Completed

Last Edited
29/06/2009

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Quality of life

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

ROR
https://ror.org/03ra42c27

Funder(s)

Funder type
Industry

Funder Name
DexCom Inc. (USA)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes