DOES PREDICTED LOW SUSPEND PUMP TREATMENT IMPROVE CONTROL AND QUALITY OF SLEEP IN CHILDREN WITH TYPE 1 DIABETES AND THEIR CAREGIVER ?

THE QUEST STUDY : QUALITY OF CONTROL AND SLEEP IN CHILDREN WITH DIABETES USING NEW TECHNOLOGY

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BACKGROUND

- Fear of nocturnal hypoglycaemia amongst parents of children with Type 1 diabetes leads frequently to chronic sleep disturbances and lack of sleep for the parents as well as for their children with diabetes, with negative effects on their daily functioning and well-being.
- Sensor augmented pump treatment (SAP) is associated with decreased HbA1c levels, increased time in glucose target and reduced time spent in hypoglycaemia.
- Alerts programmed and used in SAPs in order to inform patients and their caregivers about hypo-and hyperglycemic events allow them to respond quickly to such glycemic excursions. Alerts, however, can be perceived as disturbing.
- The Flash Glucose Monitoring (FGM) device, Freestyle libre® is another method to obtain continuous interstitial glucose measurements, but the results can only be obtained when the patient/caregiver actively scans the sensor: no alerts are given as no communication exists between the glucose measurement and the insulin pump. The advantage of the FGM is the access to 24h glucose profiles without disturbing alerts.

OBJECTIVE

Evaluation of two different glucose monitoring methods and their impact on time in glucose target, sleep and quality of life in children with type 1 diabetes and insulin pump treatment and one of their caregiver.

DESIGN

Open-label, single-centre, randomised, crossover study

INCLUSION CRITERIA

- age : 6-14 years
- type 1 diabetes duration ≥ 6 months
- on insulin pump ≥ 6 months
- HbA1c ≤ 11%
- written informed consent of the primary caregiver, assent of the patients

METHODS

Subjects are randomized to one of the 2 glucose measurement methods: SAP with the SmartGuard feature (640G Medtronic®) or insulin pump with independent continuous glucose measurement (Freestyle libre®). The sequences are either SAP for 5 weeks followed by a 3 weeks washout interval and the FGM for 5 weeksor the reverse. The week before and in the last week of each period the subjects and one of their caregivers wear a sleep monitor (Actigraph®) and complete a sleep diary. Glucose target is defined as 3.9 - 8.0 mmol/l during the final 6 days.

RESULTS

Recruitment started in March 2017. A total of 32 patients are planned to be included. Study completion is anticipated in April 2018.

CONCLUSION

This study will evaluate a potential impact of SAP with SmartGuard® feature on time in glucose target, sleep quality, quantity and quality of life perception in patients with T1DM and their primary caregivers, when compared to pump treatment with Flash Glucose Monitoring device.

ClinicalTrials.gov Registration: NCT03103867

OUTCOME

Primary outcome

- Between arm differences in percentage of time in glucose target (3.9 – 8.0 mmol/l) during the final 6 days of each treatment arm, measured by a blinded CGM (IPro2®).

Secondary outcome

Comparison of the two periods:

- Percentage of time below glucose target (< 3.0 mmol/l and < 2.5 mmol/l) as measured by blinded CGM (iPro2®)
- Percentage of time above glucose target (> 10 mmol/l)
- Total sleep and wake time, number of awakenings as measured by Actigraph®
- Quality of sleep in patients and in one of their caregivers (Epworth sleepiness scale)
- Quality of life perception in children and in one of their caregivers
- Hypoglycemia fear survey in children and one of their caregivers
- Impact of family responsibility scale on total sleep and wake time, number of awakenings
- Impact of time in glucose target on total sleep , number of awakenings
- Daily physical activity as measured by Actigraph®
- Severe hypoglycemic events

STATISTICAL ANALYSIS

Time in glucose target (3.9 -8.0mmol/l) will be evaluated by the blinded CGM in both treatment arms
Sleep duration will be analysed using a linear mixed model with treatment given and period of treatment as fixed effects factors and patient as a random effect.

Actigraph®

IPro2

Treatment arm A

Treatment arm B

V0   V1   V2   V3   V4

28 days period   28 days period

Actigraph + IPro2 | Actigraph + IPro2 | Actigraph | Actigraph + IPro2

-7   1   7   21   28   49   70   77   *days*

Information / Informed Consent / Randomization

CRF V0 / Questionnaires Children and Parents (C+P) / Sleep Diary C+P

CRF V2 / Questionnaires C+P / Sleep Diary C+P

CRF V3 / Questionnaires C+P / Sleep Diary C+P

CRF V4 / Questionnaires C+P / Sleep Diary C+P

Arm B-A Actigraph + IPro2 | Usual treatment → Start treatment 640G with SmartGuard | Actigraph + IPro2 | Wash out | Actigraph | Cross over to treatment Freestyle Libre (FGM) | Actigraph + IPro2

Arm A-B Actigraph + IPro2 | Usual treatment / Start treatment 640G with Freestyle Libre FGM | Actigraph + IPro2 | Wash out | Actigraph | Cross over to treatment 640G with SmartGuard | Actigraph + IPro2