CAN AN AUTOMATED CLOSED LOOP SYSTEM IMPROVE OUTCOME IN ADOLESCENTS WITH POORLY CONTROLLED TYPE 1 DIABETES ?

THE SPIDIMAN 02 STUDY

SPIDIMAN
Single Port Insulin Infusion for Improved Diabetes Management

U. SCHIERLOH[1], G. AGUAYO[2], M. FICHELLE[1], D. SCHAEFFER[1], A. CELEBIC[2], M. VAILLANT[2], M. E. WILINSKA[3], R. HOVORKA[3], C. DE BEAUFORT[1] AND THE SPIDIMAN STUDY GROUP | **S**INGLE **P**ORT **I**NSULIN INFUSION FOR IMPROVED **DI**ABETES **MAN**AGEMENT

BACKGROUND

Good metabolic control during adolescent years reduces the risk of microvascular complications as young adults. The majority of youth doesn't meet the HbA1c targets.

RESULTS

Recruitment started in July 2017. Twelve to fifteen patients will be randomized with completion in June 2018.

OBJECTIVE

This study aims to evaluate efficacy, safety and acceptability of the automated closed-loop glucose control (CL) 24/7 over 4 weeks in comparison with continuous subcutaneous insulin infusion in home setting in poorly controlled adolescents with type 1 diabetes.

CONCLUSION

This study will evaluate whether automated closed loop treatment can improve control and quality of sleep in adolescents, as well as the acceptance of parents to allow adolescents to take his/her responsibility in diabetes management.

DESIGN

Open-label, single-centre, randomised, cross over study

INCLUSION CRITERIA

- age : 12-18 years
- type 1 diabetes duration ≥ 1 year
- on insulin pump ≥ 6 months
- HbA1c ≥ 8,0% ≥ 6 months
- written informed consent of the primary caregiver, assent of the patients

METHODS

Subjects with type 1 diabetes are randomized to CL treatment (Florence D2A) with Model Predictive Control (MPC) algorithm and the study pump (Dana, SOOIL) or to their usual treatment with insulin pump and continuous glucose measurement (CGM). After 4 weeks they switch to the other treatment. Before and during the last treatment week, subjects wear a sleep monitor (Actigraph®) to record sleep data. Quality of life perception and impact on family responsibility will be evaluated by questionnaires at the end of each treatment arm.

OUTCOME

EFFICACY :

Time in glucose target (%) 3.9 - 10.0 mmol/l) measured prior to the start of treatment and during both 4 week treatment arms by CGM (Freestyle Libre Pro).

SAFETY :

Episodes and severity of hypoglycaemia (< 3.0 mmol/l and < 2.5 mmol/l), and nature and severity of ketoacidosis and other adverse events during both treatment arms.

ACCEPTABILITY :

Assess the duration of use (%) of the automated system, perception of quality of life, perception of quality of control.

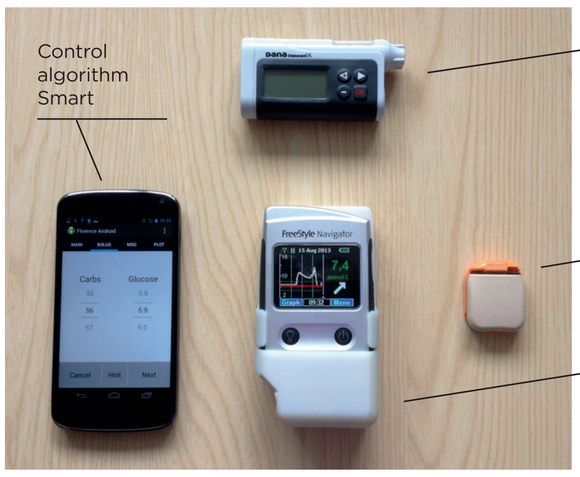
ADDITIONAL ENDPOINTS

- Comparison of 7 days sleep data (quantity of sleep and awakenings), evaluation by Actigraph® data.
- Quality of life perception (questionnaire) of the subjects and one of their caregivers
- Impact on family responsibility (questionnaire) before and after each treatment arm
- Time spent above glucose target (%) (> 10 mmol/l) during the 4 week treatment arms based on a between arm comparison.
- Use of the CGM during the open loop period.
- Quality of life perception in adolescents before and after the 4 week treatment arms
- User experience after the 4 week treatment arm with closed loop (questionnaire).

STATISTICAL ANALYSIS

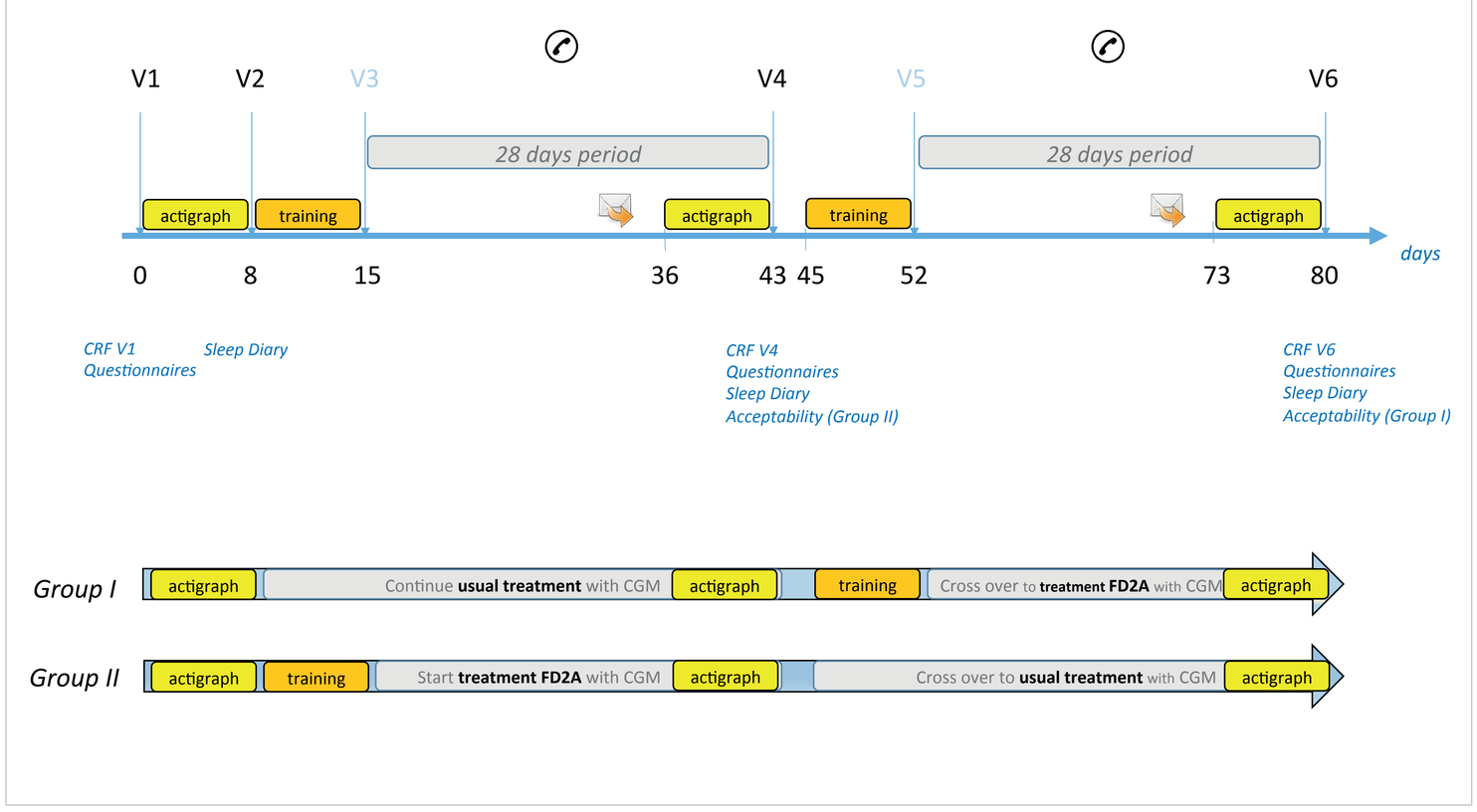
Primary analysis will be a single comparison and no attempt will be made to formally control the overall type I error rate for the secondary/exploratory outcomes.
A 5% significance level will be used to declare statistical significance for the primary comparison.
Severe hypoglycaemic events and diabetes ketoacidotic events necessitating hospitalisation, will be tabulated in each treatment group.
Severe hypoglycaemia events will be tabulated irrespective of whether CGM data are available and irrespective of whether closed-loop was operational.
A severe hypoglycaemic event will be defined as an event requiring assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions. This is a feasibility study: power calculation does not apply.

Image FlorenceD2A closed-loop system



Freestyle Libre Pro

Actigraph®



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1 CHL Centre Hospitalier de Luxembourg KANNERKLINIK
2 LUXEMBOURG INSTITUTE OF HEALTH RESEARCH DEDICATED TO LIFE
3 UNIVERSITY OF CAMBRIDGE
JOANNEUM RESEARCH
DECCP Diabetes Endocrinology Care Clinique Pédiatrique
Cambridge University Hospitals NHS Foundation Trust