HOME USE OF THE ARTIFICIAL PANCREAS IN VERY YOUNG CHILDREN WITH TYPE 1 DIABETES: THE PILOT STUDY

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Background and aims

- The multinational KidsAP project assesses the ability of closed-loop insulin delivery to improve glucose control in children with type 1 diabetes aged 1 to 7 years
- *The KidsAP pilot study* evaluates the feasibility of closed-loop in home settings and the potential benefit of diluted insulin use during closed-loop operation given the low insulin amounts needed in this population

Methods

- The pilot study adopts an open-label, multi-centre, multinational, randomised, two-period crossover design (see Figure 1)
- Closed-loop using diluted insulin U20 and closed-loop using standard insulin U100 are contrasted
- The order of the two 3-week intervention periods is random
- FlorenceM hybrid closed-loop system is used during both arms (see Figure 2)
- Up to 30 children aged 1 to 7 years with type-1 diabetes will be recruited at 7 European diabetes centres
- Primary outcome is time spent with sensor glucose in target range (3.9 and 10.0 mmol/l)
- Secondary outcomes include mean glucose, time spent with glucose levels in hypo- and hyperglycaemia

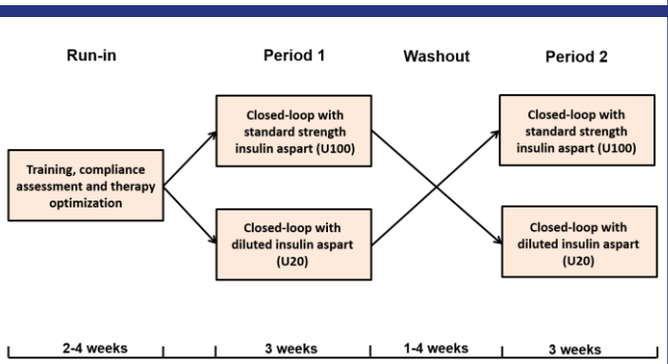

Figure 1. Study design of the KidsAP pilot trial

Declaration

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Figure 2. FlorenceM closed-loop system

Results

- Recruitment started in August 2017.
- Through September 2017, 3 participants were enrolled
- One randomised participant (5 years, female, HbA1c 47mmol/mol, total daily insulin dose 12U/day) completed the first arm (U100).
- Her percentage of time in target was 71%, mean glucose was 8.0mmol/l, time spent in significant hypoglycaemia (<3.0mmol/l) was 1.8% (see Figure 3)

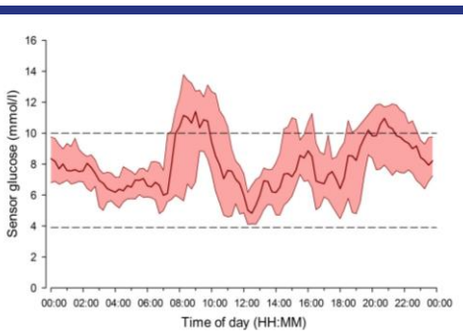

Figure 3. Sensor glucose during 3 weeks of 24/7 closed-loop using standard strength insulin in one subject (median, interquartile range).

Conclusions

- The study will assess feasibility of home use of closed-loop in very young children
- The study will provide insights into safety, utility and user-acceptance of closed-loop in this age group
- The study will determine the role of diluted insulin during closed-loop use