Artificial Pancreas Studies Cambridge

Winter 2009/2010

Newsletter

Our third year of Artificial Pancreas (AP) studies has been very productive and we have been able to collect valuable data from two more paediatric studies, two adult studies and one study of diabetes in pregnancy. All our research studies have been carried out in the Wellcome Trust Clinical Research Facility (WTCRF) on the Addenbrooke's site.

REMINDER OF PREVIOUS STUDIES

In 2007 and 2008 we completed our first three studies involving children and adolescents. We started by comparing overnight glucose control on standard pump therapy (known as CSII) with glucose control using the Artificial Pancreas (known as Closed-Loop). The results showed that the Artificial Pancreas improved glucose control and reduced the risk of hypoglycaemia.

Six children from the first study then volunteered to help us test the Artificial Pancreas further after eating a meal composed on one night of rapidly absorbed carbohydrates and on the other night of slowly absorbed carbohydrates. The results were similar to those obtained from the first study, indicating that the Closed-Loop system can improve glucose control, even after large meals irrespective of their composition.

The third study concentrated on testing the Artificial Pancreas after exercise. The nine children and adolescents who took part exercised during the evening and then linked up to the Artificial Pancreas overnight. The results showed greatly increased time in target and reduced risk of hypoglycaemia. The Exercise Study was completed by the end of 2008.

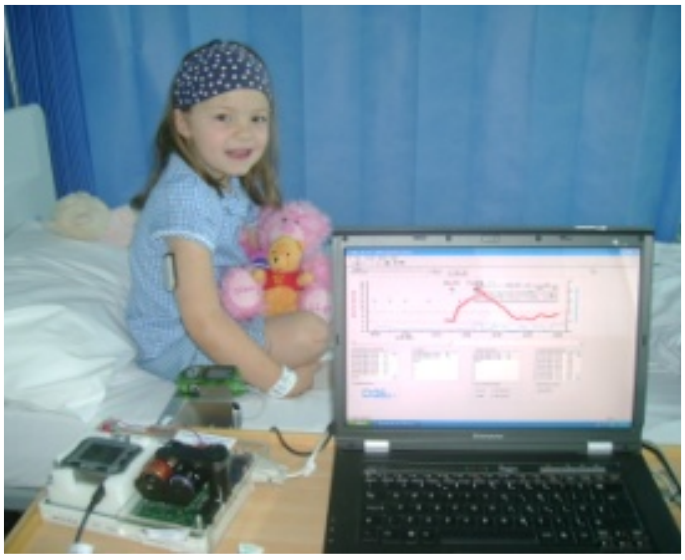
NEW STUDIES IN 2009

Meal Absorption Study

Eight young people between the ages of 16 and 24 were involved in this study, The aim was to find out how quickly glucose from an evening meal is absorbed into the blood stream. This information will help in adjusting insulin boluses. Also it will help us to understand more about glucose excursions and will contribute to the development of the closed-loop system. The study is still continuing and we will be able to report on our findings in the next newsletter.

Automated Closed-Loop in Children and Adolescents

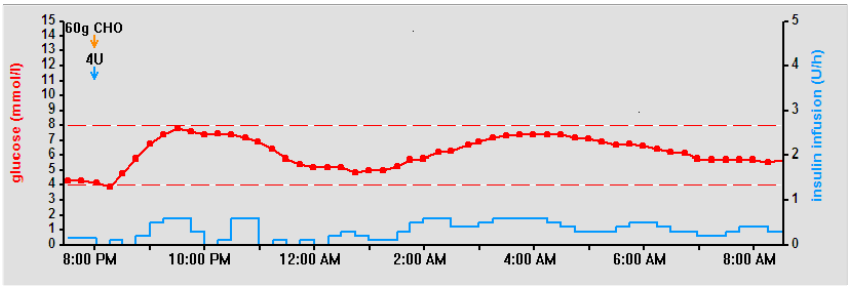
Eight children and adolescents between the ages of 6 and 18 years have helped with this study which used a prototype of a fully automated closed-loop system comprising a computer, Continuous Glucose Monitor and insulin pump operated remotely.



The study is still continuing, but the results so far are encouraging. We hope to recruit another eight children in 2010 to complete the study. The next stage will be to run a similar study at home next year.

Pilot Study in Adults

For our first study in adults we compared overnight closed-loop control directly with conventional insulin pump treatment. The study commenced in February 2009 and lasted for 5 months. The results demonstrated improved glucose levels, similar to the results in children. The following chart shows an example of one subject's steady blood glucose when using the Artificial Pancreas.



Alcohol Study

Our second adult study looked at the control of blood glucose levels overnight after an evening of drinking alcohol. Twelve subjects were recruited to come to the WTCRF on two occasions. On one night their blood sugar was controlled by their standard pump therapy and on the other night the closed-loop system advised insulin delivery and the pump was changed manually every 15 minutes by the nurses.

This study has only just been completed and the results are in the process of being analysed, but so far look promising.

Pregnancy Study

The first pregnancy study started in March 2009 and is still continuing. So far, nine expectant mothers have been tested in early pregnancy and five have been studied again in late pregnancy comparing their performance using the closed-loop system compared to conventional treatment.

Results cannot be analysed until both stages of the study have been completed and will be reported in the next newsletter.

FUTURE STUDIES

The research continues. There are several more studies now being planned and the first of these will start early in 2010.

Meal absorption study in Young People with Type 1 Diabetes

We have obtained approval of an extension to the study carried out in 2009 which looks specifically at the absorption of a rapidly absorbed carbohydrate meal. Again this is to help us understand the size of bolus required to cope with different types of food and improve glucose control around meal-times.

36 hour study in children and adolescents

We are keen to assess the effect of using the Artificial Pancreas over a prolonged period which includes normal daytime activities. We shall compare two identical 36-hour periods. Twelve young people, ranging in age from 12 to 18 years, will each spend two nights and one day in the WTCRF on two separate occasions. During that time we shall compare their normal home therapy against their control using the closed-loop.

Home studies in children and adults

We are planning home studies to take place next year using the Artificial Pancreas overnight.

Pregnancy study

Our next pregnancy study will test the use of the Artificial Pancreas during the daytime when patients are undertaking normal activities rather than lying in bed.

THE AP RESEARCH TEAM

Back row (left to right): Ms Josephine Hayes, Professor David Dunger, Dr Carlo Acerini, Dr Roman Hovorka, Dr Helen Murphy, Mr Jasdip Mangat, Dr Mark Evans

Front row (left to right): Dr Daniela Elleri, Ms Marianna Nodale, Ms Julie Evans, Dr Malgorzata Wilinska, Ms Janet Allen, Dr Kavita Kumareswaran

OTHER NEWS

Our team continues to expand to meet the growing demands of our many studies. We have been joined by another clinician, Dr Kavita Kumareswaren, from Wellington in New Zealand. We are also enjoying some assistance from two students who are involved in mathematical modelling, which helps to forecast the probable results of implementing different treatments. James Graveston is an undergraduate of St John's College, Cambridge, and Ahmad Haidar is visiting from McGill University in Quebec, Canada.

We have had scientific papers accepted for publishing in many professional journals including, recently, The Lancet, who will publish an article on our research early in the New Year.

Members of the research team presented some of the results at several international meetings and conferences in 2009, including meetings in Greece, Slovenia, Austria, and several different locations in USA. In addition, presentations were made in UK to invited audiences at meetings organised by MHRA (Medicines & Healthcare Products Regulatory Agency) and JDRF (Juvenile Diabetes Research Foundation).

With the assistance of Mr John Davis of INPUT (INsulin PUmp Therapy), a patient-led support group for people using insulin pumps to control their diabetes, we are about to conduct a survey into attitudes and problems encountered by children and adolescents in managing their diabetes.

ACKNOWLEDGEMENTS

We wish to extend sincere thanks to the following for their continuing support in our work:

- Wellcome Trust Clinical Research Facility and their staff, who make it possible for us to run our studies in Cambridge
- Norfolk and Norwich university Hospital Department of Paediatrics, who help to identify and refer to us suitable patients from their clinics
- Cambridge University Department of Paediatrics, who analyse study samples in their laboratories
- JDRF, who have funded our overnight paediatric studies
- Diabetes UK, who have funded our adult and pregnancy studies
- NIH (National Institutes of Health, USA) who are funding our new 36-hour paediatric study
- NIHR (National Institute of Health Research), who provide additional financial and infrastructure support

and finally, and **most important of all**:

- the many patients and volunteers who have taken part in the studies, without whose participation none of our research would be possible

HIGHLIGHTS 2009

- Progress in a paediatric study including the use of an automated system.
- Start of a meal absorption study in young adults
- Completion of two adult studies.
- Start of the first study in pregnancy.
- Preparations for the 36-hour children's study and the 24-hour pregnancy study, focusing on testing the system after normal daily activities.
- Continuing preparation for the home studies.