AP@home

Bringing the Artificial Pancreas home

AP@home will provide an artificial pancreas with automated closed loop glycaemic control for insulin treated patients with diabetes. The aim of the project is to simplify diabetes care and improve the quality of life for patients with diabetes.

Objectives of the project

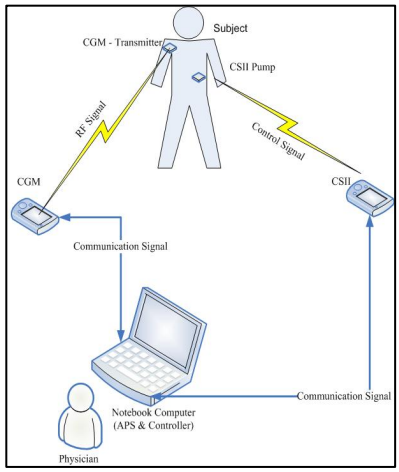
Diabetes is taking on epidemic proportions with over 220 million individuals affected by this disease worldwide, a number which is expected to grow to 350 million by the year 2030. Roughly one third of people with diabetes are treated with subcutaneous insulin injection treatment. To determine the dose for their insulin injections they not only have to monitor their blood glucose concentration frequently by means of a finger prick, but also they have to consider the influence of meals and exercise on their glucose homeostasis. Maintaining glucose levels in the normal range is essential for preventing diabetes-related complications, including microvascular complications like nephropathy leading to renal insufficiency, retinopathy leading to blindness, and neuropathy leading to foot ulcer or amputation as well as macrovascular complications like heart infarction and cerebral infarction with their associated mortality. However, bringing glucose levels to target using insulin therapy is limited by the frequent occurrence of hypoglycaemic episodes, i.e. too low glucose values.

The AP@home project wants to:

- Improve glucose sensing and insulin infusion
- Develop an artificial pancreas (AP) device which needs only one perforation of the skin for glucose measuring and insulin delivery
- Advance algorithms that stabilize glucose levels within the normal range
- Extend these algorithms to work under daily life conditions such as rest, sleep, meals and exercise
- Implement alarms and a telemedicine system
- Perform clinical validations
- Bring this AP device to the patients' home to study the performance of the AP system

Project Description

The AP@home project starts building a new AP device by using well established glucose sensors and insulin pumps. AP@home will develop novel methods to improve the existing glucose measuring and insulin delivery components. These improvements will lead to the creation of smart sensors and more accurate insulin delivery adaptations. In particular, we will design real-time software applications reducing sensor noise, circumventing sensor delay and assessing glucose levels more reliably in the interstitial fluid of the subcutaneous tissue. Insulin delivery algorithms will be integrated with the insulin pump and glucose sensor to create a AP device to be validated clinically in patients with diabetes. The validation will address the safety, the alarms and crisis management and efficacy under different real life situations such as night-time, exercise and meal intake as well as the concept of remote control.



In parallel AP@home will develop novel AP prototypes that only need one skin perforation and where a single catheter is used both for insulin delivery and glucose sensing.

Clinical Scenario

First clinical experiments with overnight automated closed-loop control of blood glucose with algorithms developed by research groups in Cambridge and Padua-Pavia showed an increase in time spent in euglycaemia combined with less time spent in hypoglycaemia. The advanced CAT trial now compares blood glucose control defined by the time spent in target range achieved by the two closed-loop algorithms to open loop control during night-time and daytime in a randomized three-way cross-over intervention study with 48 patients in 6 clinical centres.

For the validation of the AP prototypes under different real-life situations such as sleep, meal intake and exercise, the clinical trials comprise several safety and effectiveness studies to prepare the AP devices for use at home. In these clinical validations the main focus will be on the generation of alarms and crisis management and providing these alarms to significant others or health care professionals via remote control. This will result in a prevention of diabetes-related complications and improved patient safety.

Expected Results & Impacts & Preliminary results

The outcomes of the AP@home project will:

- Improve disease management through more precise measurement of health status and involvement of the patients in their care process, increase the worldwide access of patients to better, secure and safe personalized health systems and reduce hospitalization and its costs without compromising the health care quality and
- Reinforce the leadership and innovation of the industrial partners and contribute to the knowledge-based society and accelerate the establishment of standards on personal health systems for diabetes.

Contribution to improved health care and research

The outcomes of the AP@home project will have an impact on healthcare and scientific competitiveness. The knowledge on AP systems will increase significantly and improve healthcare and patient comfort. The closed loop systems will allow secure, swift and seamless communication of health data from the device to the patient – continuous glucose trails, hypoglycaemia alarm – and to the health care provider. The links and interaction between patients and doctors will be improved thus facilitating a more active participation of patients in the care process. The knowledge will increase the scientific competitiveness of scientists and clinicians in the diabetes field. This will lead to expansion of high-skilled jobs in pharmaceutical, therapeutics and related telemedicine services in European research and clinical organizations.

Contribution to European industrial competitiveness

The project is expected to reinforce the leadership of the industrial partners to push forward their roadmap for new solutions in the field of Personal Health Systems and medical devices. In particular we envision the possibility to develop new system architectures that could drive the realization of new eHealth solutions addressing continuous glucose monitoring, automated closed-loop control, remote alarms, and therapy for diabetes. This will lead to increased job growth in the field of telemedicine.

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KEYWORDS
Diabetes, Closed-loop, Artificial pancreas, Continuous glucose measurement, Personalised health, Telemedicine