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Single Port Insulin Infusion for Improved Diabetes Management

Mission

To improve quality of life for adult and paediatric diabetes patients

Continuous glucose monitoring (CGM) measures interstitial glucose levels in real time rather than at discrete time points. Use of CGM improves glycaemic control, particularly after meals or exercise. Commercially available CGM systems combined with an insulin pump still require two body-interface sites, or two ports; one port for glucose monitoring, and the second for insulin delivery. Such systems require handling of two devices and two body-interfaces, which results in low acceptance, particularly by paediatric patients.

SPIDIMAN aims to provide a single-port closed-loop system of continuous glucose monitoring (CGM), insulin dose calculation and continuous insulin infusion as an "all-in-one" artificial pancreas (AP) system.

In order to provide diabetes patients—especially paediatric patients— with the advantages of tight glycaemic control, SPIDIMAN plans to overcome the limitations of current diabetes management by employing an innovative optical sensor technology that will be merged with commercial insulin infusion sets.



Approach

Close cooperation of medicine and engineering

SPIDIMAN is an SME-targeted research project, and will strengthen existing collaborations and forge new links between research organisations, clinical institutions and device manufacturers. Four research-focused SMEs, three universities and two research organisations have joined forces in this project to develop the SPIDIMAN single-port artificial pancreas (AP) system, and subsequently validate its ability to improve clinical management of glycaemia in a stepwise approach. In the first trial, the sensor performance will be evaluated in type 1 diabetes patients. In the second step, the sensor will be tested in combination with the algorithm controlling the insulin infusion. The final step concerns the evaluation of the safety and efficacy of the SPIDIMAN system in children; paediatric care will benefit more than any other group, because current diabetes management is very restrictive for children, with major impacts on quality of life.

System development

The sensor

SPIDIMAN will develop a new coating technology to graft luminescent glucose-sensitive dyes onto standard insulin infusion sets to combine continuous glucose monitoring and insulin infusion.

The glucose reader

A wearable miniaturized glucose reader will be developed for reliable transcutaneous read-out of the luminescence emitted by the glucose sensor.

The algorithm

SPIDIMAN will develop control algorithms to calculate accurate insulin dosages based on the new integrated glucose sensor, with particular attention to the characteristics of children and adolescents.

Data management

All data from the preclinical experiments and clinical trials will be entered into a knowledge pool where the participating medical institutions can store and share their findings.

Patient safety

Patient safety and biocompatibility of the new single-port will be rigorously tested in full compliance with all regulations.

Preclinical trials

The performance of the new sensor technology will be validated in a preclinical trial, but will also use innovative in-silico modelling to minimise animal experimentation.

Clinical trials

SPIDIMAN will conduct investigator-driven clinical trials to validate the performance of the new single-port AP. Specific efforts will be made to adapt the new single-port AP to paediatric type 1 diabetes patients. Thus, its performance will be validated in a separate paediatric trial.

Paediatric aspects

The new SPIDIMAN AP system will be especially effective in paediatric patients, as tight glycaemic control improves the long-term health of diabetes patients. The single-port AP particularly improves the quality of life in children because it is reduces unnecessary manipulations and is suitable for children's more active lifestyles.





















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SPIDIMAN at a Glance

- ► Grant Agreement number: 305343
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