Patient satisfaction with a new smart and cost-effective Insulin Patch Pump System in type 1 diabetes patients using CSII and CGM or Flash glucose monitoring system

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To perform a patient satisfaction study on the Equil patch pump in T1DM patients that currently already use CSII in combination with CGM or Flash glucose monitoring.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON55242

Source
ToetsingOnline

Brief title
Patient satisfaction with Equil patchpump

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
type 1 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Van Heek Medical
Source(s) of monetary or material Support: van Heek Medical

Intervention

Keyword: Insulin pump, Patch pump, Patient satisfaction, Type 1 diabetes

Outcome measures

Primary outcome

Patient satisfaction compared to current CSII system

Secondary outcome

Number of perceived dysfunctions, unexpected hypo- and hyperglycaemia,

ketoacidosis

Study description

Background summary

Maintaining glycemic values at levels of nondiabetic range is efficient in preventing long-term complications of type 1 diabetes mellitus (T1D) (1,2,3). However, achieving good glucose control is challenging and still difficult to achieve for more than half of the patients. Today, thanks to the tools offered by technologies, we can aspire a more sustainable management of diabetes on a daily basis. In clinical practice, treatment of T1D patients with continuous subcutaneous insulin infusion by pumps (CSII) in combination with continuous glucose monitoring (CGM) can lead to improved glycemic control and reduction of diabetes complications thereby improving quality of life (4, 5). One drawback of the current CSII pumps is their bulky size, need for tubes thereby limiting comfort and quality of life on a day-to-day basis.
Patch pumps are novel insulin delivery systems that have emerged on the market and characterized by smaller size and absence of tubes. Such advantages meet many patient*s preference achieving clinical improvements through greater treatment adherence and greater engagement (6,7, 8). From a technical perspective, they can offer all insulin delivery functionalities as compared with conventional insulin pump delivery systems.
Some new Patch pump systems include non-disposable components with reduced costs and environmental impact. Therefore, these systems could be effective and

financially sustainable in larger cohorts of patients. The Equil patch pump has been extensively tested and has certificates from EN ISO and the European Committee (zie bijlagen). It is already used in several countries (Italy, Tsech Republic and Greece, but not yet available in the Netherlands.

Study objective

To perform a patient satisfaction study on the Equil patch pump in T1DM patients that currently already use CSII in combination with CGM or Flash glucose monitoring.

Study design

Observational

Study burden and risks

Burden:
At start and at the end of the study the patient is asked to fill in a questionnaire (about 15min)
There is one telephone call after one week (about 15min)
The patient has to fill in a diary every day (about 5 min per day)
Risks:
If the patient has technical problems with the pump, glucose values might fluctuate more then normal

Contacts

Public
Van Heek Medical

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NL
Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Male and female patients
* T1D patients <=>18 years
* Using CSII for 12 months or longer and needing a new pump within 6 months
* Using CGM or FGM
* Written informed consent obtained from the patient

Exclusion criteria

* Pregnancy or pregnancy wish
* Patients unable to understand spoken and written Dutch language
* Patients on (hybrid) closed loop systems, i.e. Medtronic 670G pump
* Patients on Medtronic 640G CSII pump that also use CGM-based *stop before low*
* Patients with unstable glucose regulation, for example frequent hypo- or hyperglycaemia
* Not able to perform the study according to the treating physician
* Severe comorbidity and/or psychiatric disease

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-01-2021
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Equil patch ibsulin pump
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-11-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	12-03-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL74682.058.20