

Validation Freestyle continuous registration of glucose for the purpose of safe and correct use in the Netherlands

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1. Clarity regarding validity and usability of the Freestyle Libre, including detailed results regarding the strengths and weaknesses associated with this new technique 2. Clear advice on follow-up projects related to long-term quality control 3....

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

Summary

ID

NL-OMON42315

Source

ToetsingOnline

Brief title

Validation Freestyle-Libre

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

Diabetes

Research involving

Human

Sponsors and support

Primary sponsor: Interne geneeskunde

Source(s) of monetary or material Support: De studie wordt uitgevoerd door mensen die al in het ziekenhuis werkzaam zijn. Het device wordt gratis geleverd door Abbott.

Intervention

Keyword: Blood Sugar, Continuous Glucose Registration, Diabetes

Outcome measures

Primary outcome

1. Validate the Abbott Freestyle-Libre glucose measurement technique used on various insertion sites, by comparing its outcomes with another continuous glucose monitoring (CGM) technique and laboratory testing as the golden standard for glucose measurement.

Secondary outcome

1. Comparing the use of the Freestyle Libre between insertion in the upper arm and abdominal insertion (currently the Freestyle Libre is only tested after insertion into the upper arm, comparative data on other places where this device can be inserted are missing)
2. Study the glucose values after eating a meal using the Freestyle Libre and venous measurements (meal clamp technique)
3. Study the influence of the use of paracetamol and vitamin C on the reliability of the Freestyle libre results.

Study description

Background summary

In people with diabetes mellitus, especially in people using insulin, regular monitoring of blood glucose levels is important. Usually, a finger prick is used. Such a finger prick is usually more painful than the insulin injection itself, and many people therefore do not check their glucose values as often as is needed. People with DM check themselves from several times a week upto more than ten times a day.

In recent years, a continuous glucose registration became available. With a few minutes intervals, glucose is measured in the interstitial fluid. However, this equipment is expensive and the usage will therefore be limited. In addition, the fact remains that the result is a glucose value in the interstitial fluid, which is lower than in the bloodstream and changes in the glucose levels in the bloodstream take time to be monitored in the interstitial fluid (estimated to be about 20 to 30 minutes).

Many people with DM and a fluctuating or poor regulation of their glucose levels would be helped with a system that measures frequently without automatic reading ability. Recently, Abbott presented the Freestyle Libre. The costs associated with the use of this form of registration are lower than those of conventional CGM. Although this seems a good solution for people with DM who, for whatever reason, need to check frequently their glucose levels, this measurement method has not yet been adequately validated. This makes it necessary to validate this potentially important and positive development.

Study objective

1. Clarity regarding validity and usability of the Freestyle Libre, including detailed results regarding the strengths and weaknesses associated with this new technique
2. Clear advice on follow-up projects related to long-term quality control
3. Clear advice on follow-up programs with respect to similar device already developed or to be developed by other companies

Study design

The current proposal has to be seen as a preliminary set of measurements, aimed at examining the reliability of the Freestyle-Libre.

Study burden and risks

There are no risks associated with participation in this study except for the risk of local pain and hematoma, like with all other CGM devices

Contacts

Public

Selecteer

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Scientific

Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Age 18-75 jaar

10 non-DM, 10 T1DM, 10 T2DM in a stable situation

Able to undergo the required controls and to fill in the questionnaires proposed

Able to perform general daily activities

Exclusion criteria

Unable to understand the study information or the Dutch language

A condition that makes the health situation unstable or which results in the short term to serious deterioration or death.

Chronic use of high doses of paracetamol and / or vitamin C

Study design

Design

Study phase: 4

Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	17-08-2015
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Freestyle Libre;Continuous Glucose Registration
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	06-03-2015
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL51993.075.14