Performance of the Freestyle Libre Version 2 isCGM in daily practice in Elderly

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To determine the accuracy of the FSL in persons >= 70 years of age with diabetes (type 1 or type 2) as compared to routine capillary measurements and whole blood measurements.

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

Summary

ID

NL-OMON56777

Source
ToetsingOnline

Brief title
Performance of the FreeStyle Libre glucose monitor (Ver. 2) in the elderly

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Elderly, Freestyle Libre, Glucose monitoring

Outcome measures

Primary outcome

Primary outcome is the accuracy of the FSL-v2 compared to Contour blue capillary measurement results during the 14-day study period.

Secondary outcome

Secondary outcomes are (i) the accuracy of the FSL during the standardized oral glucose load test and (ii) the usability and satisfaction with the FSL.

Accuracy will be analysed as according to the guidelines for Integrated Continuous Glucose Monitoring Approvals (Class II-510(K), (Parkes) error grid-, bias (including MARD), correlation, stability and Bland-Altman analysis.

Study description

Background summary

For the optimal regulation of diabetes, frequent measurements of glucose levels are essential in individuals who use insulin therapy. The Freestyle libre (FSL) is a flash glucose monitoring system, which measures the glucose levels in the interstitial fluid. It has been shown that the FSL improves glycemic control in patients and reduces the burden of disease. Its accuracy has been determined in earlier studies, however these studies included younger participants. However, in practice, the elderly form an increasingly large proportion of the FSL users, and with increased age, the interstitial space and fluid dynamics change, possibly affecting performance. As such, there is need of a formal assessment of accuracy of the FSL in the elderly population

Study objective

To determine the accuracy of the FSL in persons >= 70 years of age with diabetes (type 1 or type 2) as compared to routine capillary measurements and whole

blood measurements.

Study design

Prospective non-randomized cohort study assessing the performance of the FSL (version 2, Abbott Diabetes Care) as compared to the gold standard (capillary measurements using Contour plus blue (Ascensia Diabetes Care). Measurements will be performed during a 14-day study period which includes an in-clinic visit to perform a standardized oral glucose load test.

Study burden and risks

Participants will be asked to wear the FSL glucose monitoring devices at once and to measure their capillary blood glucose levels at regular intervals (at least 4, but preferably 7 times daily). Also, participants will undergo a 4-hour in-hospital standardized oral glucose load test, during which blood will be collected via an intravenous catheter.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

- Age >=70 years at time of inclusion
- Diabetes, type 1 or type 2
- Ability to provide oral and written informed consent

Exclusion criteria

- A history of allergies towards patch substances/adhesive;
- The inability to understand the Dutch language;
- Oral or injected steroid use within the past 3 months
- Uncontrolled thyroid disease or hypertension
- Poor visual acuity
- Inability or unwillingness to meet the protocol requirements, such as being incapacitated
- Any severe or uncontrolled medical or psychological condition which, in the opinion of the investigator, would compromise the ability to meet protocol requirements.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-03-2024
Enrollment:	26

Type:	Anticipated

Medical products/devices used

Generic name:	Freestyle Libre Version 2
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-04-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL83285.042.23