Performance of the Free Style Libre Flash Monitor versus laboratory method and the AccuChek during general anesthesia

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Primary Objective of the study: the agreement of the Free Style Libre Measurement with the laboratorium measurement and the AccuChekSecundary Objective: Delay of the interstitial glucose versus the Blood glucose measurements during an operation...

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

Summary

ID

NL-OMON46217

Source
ToetsingOnline

Brief title
Performance of the Free style Libre Flash monitor under general anesthesia

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes Mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: voorziening van materialen

Intervention

Keyword: Accuchek, Continiuos blood glucose measurement, general anesthesia

Outcome measures

Primary outcome

The amount of agreement between the measurements of the Free Style libre

monitor eand the blood glucose measured by the laboratorium.

Secondary outcome

Time delay between the changes in the blood glucose and the interstitium

measured by the laboratory measurements and teh Free Style Libre Method.

Study description

Background summary

In subjects with diabetes mellitus, adequate to good metabolic control is necessary for a variety of reasons. In subjects under general anesthesia, adequate glucose control, including prevention of hypo- and hyperglycemias, improves surgical outcomes.
One variation on earlier continue glucose monitoring (CGM) is FreeStyle Libre Flash Monitor (FLFM) an improved easiness of use and practical applicability. Relying on a CGM device implicates the assumption, that the device will be accurate and reliable.
For assessment of the accuracy and reliability the FLFM, under conditions of general anesthesia, it is proposed to perform a comparison of this device with a standard laboratory measurement during surgery under general anesthesia in patients.
In an earlier study (unpublished data) Bilo et al. had to conclude that during extreme exercise FLFM does show higher than actually present glucose levels (as assessed by capillary measurements). Bilo et al. hypothesized that increases in interstitial fluid flow contribute to reporting higher glucose concentrations compared to result with lower interstitial fluid flow in resting circumstances.
Our hypothesis is that an operation under general anesthesia is a stressful event and can be compared with exercise; however, due to supine position of the patient and no muscle activity, blood flow and thus fluid refreshment of the interstitium will be decreased. Therefore, we hypothesize that FLFM will probably measure lower glucose concentration than peripheral measured blood

glucose concentrations

Study objective

Primary Objective of the study: the agreement of the Free Style Libre Measurement with the laboratorium measurement and the AccuChek
Secundary Objective: Delay of the interstitial glucose versus the Blood glucose measurements during an operation under general anesthesia.

Study design

Fifteen patients who will be operated under general anesthesia for more than one hour. The patients have to receive an arterial catheter because of their operation or because of their health

Study burden and risks

A short needle will be brought under the skin. this needle had to be at their place 36 hours before the operation till the end of the operation.
No further risks are involved.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients under general anesthsia.
Operation time > 1 hour

Exclusion criteria

no informed consent

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2019
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Generic name:	Free Style Libre system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-04-2019
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	NL68465.075.18