Technical Study: ACCU-CHEK Inform 3 (ACI 3) Pilot Study CIM RD003651

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON48319

Source
ToetsingOnline

Brief title
ACI 3 Pilot Study

Condition

- Other condition

Synonym
diabetes; person with high glucose levels

Health condition

Geen speciale klasse, patienten met en zonder diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Roche Diagnostics GmbH
Source(s) of monetary or material Support: Roche Diagnostics GmbH

Intervention

Keyword: Diabetes, Glucose, IVD, Point-of-care

Outcome measures

Primary outcome

The primary research parameter is the blood glucose concentration. In the second phase of this study the accuracy of measurement of the ACI 3 will be determined. In the main phase, the performance of the ACI 3 on patient material is compared to the reference method.

The results of this study will not be used for for regulatory submission or approval. If study results are deemed acceptable internally, a subsequent full performance evaluation study will take place.

Secondary outcome

In order to detect and explain possible interference, the percentage of hematocrit is also determined per patient (from material of the same sample). As additional information, the use of medication and, if determined, the diagnosis of 'diabetes' is also included. The sodium concentration and measured partial oxygen pressure (pO2) are only provided if a blood gas is routinely requested.

Study description

Background summary

The ACI3 is a new meter/ test strip system for use in POCT settings (Point of Care Testing). The ACI 3 can measure the blood glucose concentration, manage data and transmit data wirelessly to a facility*s internal Data Management System (e.g hospital or laboratory information system). Diabetic, non-diabetic patients and a number of critically ill patients (IC patients) will be approached to participate in this study in order to be able to examine the accuracy of measurements of the ACI 3 on patient samples.
After informed consent, clinical data is recorded using Medrio and an Electronic Data Capture (EDC) tool. Technical data is recorded using WinCAEv (EDC).

Study objective

The primary objective of this pilot study is to determine the accuracy of measurement of the new Point of Care Test (POCT) glucose meter ACI3 from Roche Diagnostics on venous, arterial and capillary whole blood samples from adult hospital patients.
The ACI3 has been improved compared to its predecessor in both ease of use (smaller and therefore more manageable) and measuring comfort (blood is more easily transfered into the meter than before). In addition, the expectation is that by using two electrodes on the glucose measuring strip instead of one can be directly corrected for interfering substances, as a result of which the measuring accuracy increases.
The measurement accuracy is determined by comparing the results of the ACI3 meter with those of reference methods, analyzed on a Roche Cobas c501 system. The collected reference samples are coded before they are transferred to Roche Mannheim for measurement.

In order to be able to determine the measurement accuracy of the ACI 3 over the largest possible glucose concentration range more than one type of patients need to be included. Therefore, diabetic patients (usually increased glucose concentration, sometimes reduced glucose concentration) and healthy test subjects (usually glucose concentration between the reference values) are needed in this study. Also, Roche Diagnostics intends to launch the ACI 3 for use in the IC. For this purpose, it is necessary to demonstrate that the ACI 3 can also accurately measure the glucose concentration within this specific patient group.

Study design

The study is designed in three phases:
a. Familiarization phase: In this part of the study protocol, the staff is introduced to the instrument and trained on how to use the glucose test strips. The correct functions of the instrument and the operation of the test strips are verified by performing a precision experiment using quality controls. The measurement data obtained from this phase are not used for the evaluation of the ACI 3 performance.
During the familiarization phase no patient samples will be measured.

b. Initial phase: In this part, a one-day repeatability experiment will be carried out using one ACI3 instrument and the corresponding glucose test strips. For both capillary and venous whole blood three different glucose concentration ranges are tested (2.2 to 4.1 mmol / L (low), 4.2 to 11.1 mmol / L (middle), > 11.1 mmol / L (high). For each glucose concentration range, blood samples from 3 adult subjects are measured in triplicate, for which only one blood sample (venous) / finger prick (capillary) is required.
During the initial phase samples are needed from 9 aldult patients. For this part patients that come for their policlinic glucose meter checked will be asked for informed consent. The needed samples will be collected as part of their regular patient care. There will be no collection of additional materials.
If the ACI 3 meets the proposed criteria, the study can enter the main phase:
- Glucose concentration < 4,2 mmol/L (75 mg/dL): SD < 0,33 mmol/L (6 mg/dL).
- Glucose concentration * 4,2 mmol/L (75 mg/dL): CV * 6%.

c. Main phase: A comparison between the measurement results of the ACI3 with the reference method will be performed on different cohorts:
- about 60 arterial samples from adult diabetic or non-diabetic patients, of which at least 10 intensive care (IC) patients.
For these patients the study consists of a comparison between a measurement on the ACI 3 and the reference method. They will not have an additional finger puncture.

- about 60 venous of adult diabetic or non-diabetic patients, of which at least 10 intensive care (IC) patients.
For these patients the study consists of a comparison between a measurement on the ACI 3 and the reference method. They will not have an additional finger puncture.

- about 80 capillary samples from adult diabetic or non-diabetic patients, NO IC patients needed.
The capillary samples are requested by their physician for a glucose POCT measurement. Simultaneously, the glucose is also measured on the ACI 3 glucose meter. There willnever be an additional finger puncture.

The measurements on the ACI3 are performed on location (Catharina Hospital Eindhoven). The samples for the reference method are coded and sent to Mannheim, where they will be measured.
In addition to the glucose measurement, the percentage of hematocrit is determined per patient (from material of the same decrease). As additional information, the medication use and, if determined, the diagnosis 'diabetes' is included.
The sodium concentration and measured partial oxygen pressure (pO2) are only provided if a blood gas is routinely performed.
NB. The added study protocol is an official, but general version applicable to all hospitals involved. For the Catharina Hospital it has been decided not to include the pediatric and neonatal patients in this technical validation. This has been confirmed in the site-specific protocol (K6 - version 2) that is also included.

Study burden and risks

There is noadditional risk for the patient. The burden only consists of reading and possibly signing the information letter and the associated informed consent form:
A quality analysis will be carried out between a new glucose POCT meter (ACI 3) and a reference method. Almost the entire validation can be performed on residual material from patient samples that are routinely drawn (all venous and arterial samples).
Patients are already regularly checked for their glucose concentration by means of a currently in use POCT device at Catharina Hospital. A good example of this is the patients with diabetes, who come to check their glucose home meter. In addition, the glucose concentration gets checked about 100,000 times per year in clinical patients by means of a POCT measurement. For both patient groups, a finger prick provides sufficient material to also measure the glucose on the ACI 3.
Only the capillary samples used in the main phase of this validation, require additional material for the comparison with the reference method, in addition to the required whole blood for the glucose measurement (routine collection). This is, strictly speaking, not residual material, but can be obtained from the same finger prick because of the small volume (maximum 160 uL) and therefore does not provide an extra treatment for the patient. This method of blood collection is also routinely used in patient groups where a venous blooddraw is not possible. For the use of the residual material, the retrieval of the medication data and the diagnosis of diabetes and / or the additional removal of a maximum of 160uL of capillary blood during a routine finger prick informed consent will be requested from the patient.

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

Adult
Signed informed consent (before admittance to the ICU after scheduled operation).
Diabetic and non-diabetic

Exclusion criteria

Minor (< 18 year)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-06-2019
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	Glucose POCT meter
Registration:	No

Ethics review

Approved WMO

Date:	12-06-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL69448.100.19