Technical Study: Analytical Performance Evaluation of cobas pulse CIM RD005298

Published: 27-08-2020
Last updated: 09-04-2024

The aim of this study is to determine the measurement accuracy of Roche Diagnostics' new Point of Care Test (POCT) glucose meter Cobas Pulse (formerly ACI3) on venous, arterial, and capillary whole blood samples from adult hospital patients...

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

Summary

ID

NL-OMON49944

Source
ToetsingOnline

Brief title
Cobas pulse performance in practice

Condition

- Other condition

Synonym
diabetes or patient with dysglycemia

Health condition

geen speciale klassen, patienten met en zonder diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Roche Diagnostics Operations, Inc
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 glucose concentration. To assess whether the Cobas Pulse shows sufficient measuring accuracy when used in practice, the following assessment criteria are used:

1. Precision:

- samples with a glucose concentration <4.2 mmol / L (75 mg / dL) the SD is * 0.3 mmol / L (6 mg / dL).

- samples with a glucose concentration * 4.2 mmol / L (75 mg / dL) the CV is <6.0%.

2. Trueness:

- * 95% of the glucose results of samples with a glucose concentration <4.2 mmol / L (75 mg / dL) correspond well with the results of the reference method (difference maximum 0.7 mmol / L; 12 mg / dL) .

- * 95% of the glucose results of samples with a glucose concentration * 4.2 mmol / L (75 mg / dL) correspond well with the results of the reference method (difference maximum 12%).

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- * 98% of the glucose results from samples with a glucose concentration <4.2 mmol / L (75 mg / dL) correspond well with the results of the reference method (difference maximum 0.8 mmol / L; 15 mg / dL) .
- * 98% of the glucose results of samples with a glucose concentration * 4.2 mmol / L (75 mg / dL) correspond well with the results of the reference method (difference maximum 15%).

Secondary outcome

In order to detect and explain possible interference, the hematocrit, the sodium concentration and the partial oxygen pressure (pO2) are determined in addition to the glucose measurement per patient (on the iStat from material of the same sample). As additional information, the medication used and, if established, the diagnosis is also sent.

Study description

Background summary

Roche Diagnostics has developed a new POCT device (Cobas Pulse; formerly ACI 3) that can measure a patients glucoseconcentration next to or near the patient's bed. In addition, this meter can manage data itself and forward it to the hospital information system (ZIS).
A previous study has already tested whether this device can measure the glucose concentration correctly (ACI 3; NL69448.100.19). In this follow-up study, the usage and accuracy of measuring of the glucosemeter is tested in practice, by having the measurement carried out by employees who normally work with POCT equipment in their function. These so-called operators must train themselves for measuring with the Cobas Pulse using the supplied instructions.
In order to determine the accuracy of measurements of the Cobas Pulse by operators in practice, blood from hospital patients (venous, arterial and capillary) of the same sample is measured both on the new glucose meter, on an already qualified routine glucose meter and on a reference method. By comparing

the results with each other, the measurement accuracy when using the new glucosemeter can be determined in practice .
This study is designed in such a way that, after a positive evaluation, the requirements for both CE marking according to IVDD and IVDR in Europe as well as an FDA 510 (k) and a CLIA statement in the United States can be met.

Study objective

The aim of this study is to determine the measurement accuracy of Roche Diagnostics' new Point of Care Test (POCT) glucose meter Cobas Pulse (formerly ACI3) on venous, arterial, and capillary whole blood samples from adult hospital patients when used in practice .
The Cobas Pulse has been improved compared to its predecessor in both ease of use (smaller and therefore more handy) and measuring comfort (blood is easier to draw than before). A previous study has already tested whether this device can correctly measure the glucose concentration (ACI 3; NL69448.100.19). In this follow-up study, the use and accuracy of measuring the glucose meter is tested by having the measurement carried out by employees who normally work with POCT equipment in their function in practice .

Measurement accuracy is determined by comparing the results of the Cobas Pulse with those of reference methods analyzed on a Roche Cobas 6000. The collected reference samples are coded and transferred to Roche for measurement. As in the ACI 3 study, residual material obtained from regular blood samples (requested by the treating physician) is used as much as possible.

Study design

The study is designed in two phases:
a. Introductory phase: In this part of the study protocol, employees who normally work with POCT equipment are introduced to the instrument and the glucose test strip to be used. These employees, also called "operators", must train themselves to measure with the Cobas Pulse using the supplied instructions. In the unlikely event that the operation of the device with the supplied instructions is not clear, a telephone number is available for help questions.
In addition to measuring the glucose concentration with the Cobas Pulse, the glucose concentration will also be measured on an already qualified glucose meter from another manufacturer (Nova StatStrip). For the use of this glucose meter, the operators are trained under supervision, by measuring control samples.
The preparation of the reference samples is not carried out by an operator, but after training by an employee of the laboratory.

b. Main phase: The Cobas Pulse will be tested on measuring precision and measuring accuracy in practice. The measurement precision will be determined by

two operators, who will measure both regular control and linearity control samples for six days each.
A comparison between the measurement results of the Cobas Pulse with the reference method to determine the measurement accuracy in practice will be carried out on different cohorts:
* About a 100 arterial + venous samples from adult diabetic or non-diabetic patients, of which at least 10 are from intensive care (IC). All measurements on arterial samples are performed on residual material.
* About a 100 venous from adult diabetic or non-diabetic patients, of which at least 10 from intensive care (IC). All measurements on venous samples are performed on residual material.
* About a 100 capillary samples from adult diabetic or non-diabetic patients, NO patients requiring intensive care (IC). A finger prick is required for this. It is expected that a fingerstick is sufficient to measure on both the Cobas Pulse and the Nova StatStrip.
In addition to the glucose measurement on the Cobas Pulse, the glucose will also be measured on the Nova StatStrip. Both measurements are performed on location (Catharina hospital Eindhoven or Isala Clinics).
The sodium concentration, the hematocrit and the partial oxygen pressure (pO2) will be meausred with an Aboot IStat in each patient. These measurement data are also recorded. As additional information, the medication used and, if established, the diagnosis is sent along. The samples for the reference method are coded before being send to Roche Indianapolis, where they will be measured.

NB. The added study protocol is an official but general version applicable to all hospitals involved. It has been decided for the Catharina Hospital and the Isal Clinics to not include pediatric and neonatal patients in this validation. This has been confirmed in the site-specific protocol that has also been added.

Study burden and risks

There is no additional risk to the patient. The tax only consists of reading and possibly signing the information letter and the accompanying informed consent form.
A quality analysis will be performed between the new glucose POCT meter (Cobas Pulse) and a reference method when used in practice. Almost all of the validation can be performed on residual material from patient samples that are routinely collected (all venous and arterial samples).
Within Catharinea Hospital and Isala Clinics, patients are already regularly checked for their glucose by means of a POCT device that is currently being used. A good example of this is the patients with diabets who come for a regular check-up in which their glucose meter at home is checked. In addition, the glucose concentration is also checked in clinical patients about 100,000 times a year by a POCT measurement. For the capillary samples only, additional material will be collected in addition to the whole blood required for the routine glucose measurement for a measurement on the Cobas Pulse and the Nova StatStrip. Strictly speaking, this is not residual material, but for both

patient groups, a fingerstick provides sufficient material to be able to measure on the Cobas Pulse and the Nova StatStrip in addition to the routine meter. Only in a few cases will a second finger prick be requested to be able to perform all measurements (estimate <2%). The finger prick is seen as one of the least invasive ways to draw blood, which is often used in the hospital with patient groups that are difficult or non-venous to prick.
An informed consent form will be requested for the use of the residual material and / or the additional collection of a maximum of 100 µL of capillary blood during a regular blood collection, the search for the medication data and the diagnosis.

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 (for critically ill, 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):	21-01-2021
Enrollment:	600
Type:	Actual

Medical products/devices used

Generic name:	Glucose POCT meter
Registration:	No

Ethics review

Approved WMO

Date:	27-08-2020

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-09-2020
Application type:	Amendment
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	NL73544.100.20