Symphony Trial: Investigating the accuracy and reliability of the Symphony® Continuous Glucose Monitoring System at the intensive care unit

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The purpose of this study is to evaluate the safety, accuracy and performance of the Symphony CGM System in patients admitted to the Intensive Care Unit (ICU). The Symphony CGM system will be evaluated for 24 hours in ICU patients who meet the...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON38929

Source
ToetsingOnline

Brief title
Symphony Trial

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Echo Therapeutics Inc. ,EURO 99.475

Intervention

Keyword: continuous glucose monitor, glucose, intensive care unit, non-invasive

Outcome measures

Primary outcome

Main study parameters will include reference analyzer blood glucose values,

Symphony glucose values and duration of sensor use. The Safety Endpoint will be

assessed using a dermatological erythema skin scale. The subject will be

evaluated using a four point scale.

Secondary outcome

N/A

Study description

Background summary

Critically ill patients admitted at the intensive care unit (ICU) commonly develop hyperglycemia, hypoglycemia, and glycemic variability following major surgery and medical illness. Continuous glucose monitoring (CGM) in ICUs has the potential to improve glycaemic control and thereby enhance patient safety and outcomes. The Symphony CGM System is a non-invasive transdermal real-time glucose sensor to identify glucose trend data and to help maintain a hospitalized patient*s glucose levels in the desired range, while minimizing the risk for hypoglycaemia.

Study objective

The purpose of this study is to evaluate the safety, accuracy and performance of the Symphony CGM System in patients admitted to the Intensive Care Unit (ICU). The Symphony CGM system will be evaluated for 24 hours in ICU patients who meet the inclusion criteria for the study and for whom glycaemic control is

indicated.

Study design

Non-randomized, open-label trial

Study burden and risks

The potential risks related to the abrasion site and sensor placement include erythema (common), skin irritation (common) and infection (rare). The Symphony CGM System has been used in a number of other clinical trials with no adverse events. Blood sampling risks will be reduced by using an existing arterial line during the study period using techniques to minimize the amount of dead-space blood loss. Approximately 1 mL of blood per sample will be discarded, for a maximum of 40 mL blood loss during the study. It is expected that this protocol will yield increased knowledge about the accuracy of the Symphony CGM reported glucose levels and CGM reliability. The scientific knowledge which could be gained from this research is a fair balance to aforementioned minimal risks.

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

- Age * 21 years;
- Diabetic and non-diabetic patients with an anticipated stay of 24 hours of admission to intensive care
- Expected to be admitted to the ICU after elective cardiothoracic surgery and expected to require glycaemic control;
- Patient or surrogate understands and signs informed consent document.

Exclusion criteria

- History of allergic reaction to medical adhesives
- History of allergic reaction to alcohol antiseptic solution or wipes
- Abnormal skin at the anticipated glucose sensor attachment sites (burn, inflammation, infection, rash, and/or tattoo)
- History of severe congenital immunodeficiency or HIV infection
- Pregnant by history or pregnancy test
- Current participation in an industry sponsored drug or device clinical trial during the proposed 24 hour study period
- Any other clinical condition, at the discretion of the physician investigator
- Life expectancy of less than 48 hours
- Patient expected to need an MRI during the 24 hour study period. If patient unexpectedly to need an MRI, the Symphony sensor must be removed prior to the MRI.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	23
Type:	Anticipated

Medical products/devices used

Generic name:	Symphony continuous glucose monitoring system
Registration:	No

Ethics review

Approved WMO

Date:	28-10-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL45661.018.13