Study Protocol - Interventional study with product or medical device

Study Title: "Diagnostic Accuracy of ECG-less gated Cardiac CT in Resuscitated Cardiac Arrest survivors"

Study Acronym: "Optimizing Post-Arrest Evaluation with ECG-less gated Cardiac CT" (OPEN CCT Arrest)

Protocol Version and Date:
Version 1, March 4th 2025.

Registry Number: /

Investigational Product or Medical Device: Revolution Apex Elite Computed Tomogrphy Scanning Systems, GE Medical Systems LLC

Sponsor: UZ Brussel

Coordinating/Principal Investigator: Bert Popelier

Study Start Date: 01-06-2025

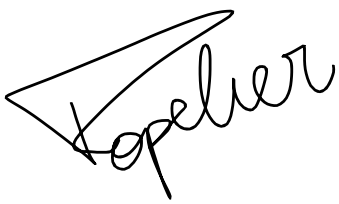
Expected Study End Date*: 31-05-2027

*In case of extension of study end date → a new date must be submitted to the EC via an amendment and the insurance department must be notified regarding the extension.

PROTOCOL SIGNATURE PAGE

I agree:

- to assume responsibility for the proper conduct of this study
- to conduct the study in compliance with this protocol and any future amendments
- not to implement any deviations from or changes to the protocol without prior review and written approval from the Ethics Committee, except where necessary to eliminate an immediate hazard to the subjects, or for administrative aspects of the study (where permitted by all applicable regulatory requirements)
- that I am thoroughly familiar with the appropriate use of the investigational drug/medical device, as described in this protocol
- to ensure that all persons assisting me with the study are adequately informed about the investigational drug/medical device and their study-related duties and functions as described in the protocol
- that I am aware of and will comply with the current good clinical practice (GCP) guidelines and ethical principles outlined in the Declaration of Helsinki
- to conduct the study in accordance with all applicable laws and regulations

Printed name	Signature	Date
Bert Popelier		March 4th 2025

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1 Sponsor/Coordinating Investigator Information

Sponsor:
UZ Brussel

Principal Investigator:
Bert Popelier

Subinvestigator(s):
Stijn Lochy

Statistician:
Andreea Iulia Motoc

2 List of Abbreviations

ACS	Acute Coronary Syndrome
AE	Adverse Event
AR	Adverse Reaction
ATMP	Advanced Therapy Medicinal Product
AxMP	Auxiliary Medicinal Product
CABG	Coronary Artery Bypass Graft
CA	Competent Authority
CCTA	Cardiac Computed Tomography Angiography
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organisation
CPC	Cerebral Performance Category
CPR	Cardiopulmonary Resuscitation
CT	Clinical Trial
CTA	Clinical Trial Authorisation
CTIS	Clinical Trial Information System
CTR	Clinical Trial Regulation
DAPT	Dual Antiplatelet Therapy
DSMB	Data Safety Monitoring Board
EC	Ethics Committee
ECPR	Extracorporeal Cardiopulmonary Resuscitation
e-CRF	Electronic Case Report Form
EMA	European Medicines Agency
EU	European Union
FANC	Federal Agency for Nuclear Control
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
IB	Investigator's Brochure
IC	Informed Consent
ICF	Informed Consent Form

ICH	International Conference on Harmonisation
ICA	Invasive Coronary Angiography
IHCA	In-Hospital Cardiac Arrest
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
IVUS	Intravascular Ultrasound
MCS	Mechanical Circulatory Support
MS	Member State
NSTEMI	Non-ST Elevation Myocardial Infarction
OCT	Optical Coherence Tomography
OHCA	Out-of-Hospital Cardiac Arrest
PCI	Percutaneous Coronary Intervention
PI	Principal Investigator
ROSC	Return of Spontaneous Circulation
RSI	Reference Safety Information
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SmPC	Summary of Product Characteristics
SOP	Standard Operating Procedure
STEMI	ST Elevation Myocardial Infarction
SUSAR	Suspected Unexpected Serious Adverse Reaction
VA-ECMO	Veno-Arterial Extracorporeal Membrane Oxygenation

3 Protocol Version History

Version N°	Version Date	Summary of changes
1	March 4th 2025	

4 Trial Registration/Protocol Summary

Information	
Objectives:	Investigate the feasibility and diagnostic accuracy of ECG-less gated CCTA in cardiac arrest survivors without STEMI, by means of agreement with ICA.
Study population:	Cardiac arrest survivors without STEMI.
In- and exclusion criteria:	- Inclusion: o Adults (≥18 years) with sustained return of spontaneous circulation (ROSC) following in/out-of-hospital cardiac arrest. o Informed consent from patient or representative obtained before invasive coronary angiography. - Exclusion o Patients on VA-ECMO o ACS STEMI or STEMI "equivalent" ▪ New left/right bundle branch block ▪ ST segment depression in leads V1-V3, when the terminal T wave is positive and concomitant ST-segment elevation ≥ 0,5mm recorded in leads V7-V9 (posterior MI) ▪ ST-segment elevation in V7-V9 (posterior MI) or V3R-V4R (RV MI) o ACS NSTEMI with persistent ST depression despite optimal therapy, suggesting ongoing myocardial ischemia, with indication for an urgent ICA according to the treating physician. o Hemodynamic/electrical instability precluding CT imaging (as perceived by the treating physician) o Life-threatening arrhythmia potentially caused by acute myocardial ischemia o Absolute contraindications to iodinated contrast o Patients with a known non-cardiac cause of cardiac arrest (e.g., traumatic brain injury, overt hemorrhage, asphyxia/severe hypoxia due to known lung disease, trauma, severe metabolic/electrolyte derangement, or intoxication) as perceived by the treating physician, where chest CT is considered unnecessary. o Known or likely pregnancy or lactation o Severe bleeding issue (as perceived by the treating physician) precluding heparin administration during radial access coronary angiography. o Prior coronary intervention (stent implantation/CABG). o CT findings indicating a condition that precludes coronary angiography in the short term. o Patients with end-of-life care pathways. o Participation in another intervention study interfering with the research questions in OPEN CCT Arrest.
Factors of interest / Data to be collected:	Chest CT scan (as early as possible) + CT brain (+ CT abdomen if perceived indicated by the treating physician) Pulmonary embolism/aortic dissection protocol ECG-less gated CCTA Invasive coronary angiography (<24 hours after CT scan) Registration of baseline characteristics at admission Registration of in study related parameters Assessment of 90 days outcome

	Assessment of agreement between ECG-less CCTA and ICA
Endpoints:	**Primary endpoint** will be the percentage of patients correctly classified to coronary artery disease as the cause of cardiac arrest after the CT scan. **Secondary endpoints** - level of agreement between CCTA and ICA based evaluation of the degree of coronary stenosis. - Feasibility: data on coronary stenosis based on ECG-less CCTA cannot be provided or is incompletely provided. - Reasons for failure of complete CCTA reporting. - Clinical outcomes at 90 days.
Target sample size:	30 patients
Statistical considerations:	We will make use of descriptive statistics. The level of agreement will be assessed with the Weighted Kappa coefficient.

5 Background and Rationale

5.1 Overview of Relevant Literature

Acute coronary syndrome (ACS) is the most important treatable cause of cardiac arrest. In contrast with cardiac arrest survivors with ST elevation myocardial infarction (STEMI), current guidelines do not recommend unselected/routine urgent invasive coronary angiography (ICA) in the patients with cardiac arrest without STEMI[1]. This recommendation reflects existing evidence indicating that immediate invasive strategies may not confer significant benefit in this population and may even be harmful[2, 3 4], while another ongoing randomized controlled trial is investigating this[5]. Nevertheless, in COACT[2], a landmark trial investigating a strategy of immediate versus delayed coronary angiography in out-of-hospital cardiac arrest patients without STEMI, one or more culprit coronary lesions responsible for triggering cardiac arrest were identified in 40% of the total patient population. The question remains pertinent whether well selected cardiac arrest survivors without STEMI can benefit from early ICA. Yet, current available clinical tools fail to identify these patients. Markers such as clinical history, echocardiographic abnormalities, arrest rhythm (shockable/non-shockable), ECG changes other than ST-segment elevation and troponin levels lack sufficient sensitivity and specificity in a cardiac arrest setting for predicting ACS requiring intervention[6, 7, 8, 9, 10, 11].

The diagnostic value of ECG-gated cardiac computed tomography angiography (CCTA) for detection of both acute and chronic coronary artery syndrome is well established[12, 13], with recent evidence demonstrating the additional value of fractional flow reserve (FFR)-CT in ACS[14]. Nonetheless, the

need for ECG-gating remains a limitation.

Recently an ECG-less CCTA modality was developed, but its diagnostic accuracy is still under validation[15]. ECG-less cardiac or coronary CT angiography (CCTA) allows cardiac imaging without requiring an ECG signal from the patient. Thus, it eliminates the steps associated with using a patient-attached ECG monitor: skin preparation, attaching the ECG leads, checking impedance, and confirming that the leads provide an adequate ECG signal to the scanning system. Therefore, workflow is optimized, which is critical in an emergency setting. In situations where it is difficult to attach the ECG leads, such as patients in a resuscitation setting who already have diagnostic ECG leads in place or other instrumentation, it is also advantageous that there is no need for an ECG signal.

Cardiac arrest patients without STEMI and with no evident non-cardiac cause generally undergo CT imaging of head and chest for evaluation of potential causes of cardiac arrest (e.g. pulmonary embolism, acute aortic dissection, intracranial hemorrhage). While ECG-gated CCTA is considered the optimal modality for non-invasive coronary imaging, ECG-less CCTA might offer a highly interesting alternative with the advantages mentioned earlier. Other benefits include no substantially longer scanning time, no need for additional contrast injection or administration of betablockers.

In case the technique is well validated, future clinical questions could include whether ECG-less CCTA can help to identify a patient population of cardiac arrest survivors without STEMI that do benefit from early invasive coronary angiography and whether earlier treatment could improve outcome.

5.2 Study Rationale and Purpose

This study aims to investigate the feasibility and diagnostic accuracy of ECG-less gated CCTA in cardiac arrest survivors without STEMI, by means of agreement with ICA.

6 Study Objectives and Endpoints

6.1 Primary Objectives

Investigate the feasibility and diagnostic accuracy of ECG-less gated CCTA in cardiac arrest survivors without STEMI, by means of agreement with ICA.

6.2 Secondary Objectives

- level of agreement between CCTA and ICA based evaluation of the degree of coronary stenosis.
- Feasibility: data on coronary stenosis based on ECG-less CCTA cannot be provided or is incompletely provided.
- Reasons for failure of complete CCTA reporting.
- Clinical outcomes at 90 days.

6.3 Endpoints

Primary endpoint

- Percentage of patients correctly classified to coronary artery disease as the cause of cardiac arrest after the CT scan.

Secondary endpoints

- level of agreement between CCTA and ICA based evaluation of the degree of coronary stenosis.
- Feasibility: data on coronary stenosis based on ECG-less CCTA cannot be provided or is incompletely provided.
- Reasons for failure of complete CCTA reporting.
- Clinical outcomes at 90 days.

7 Research Methods

7.1 Study Design

Single-center, prospective, non randomized, interventional study.

7.2 Study Population

7.2.1 Inclusion Criteria

- Adults (≥18 years) with sustained return of spontaneous circulation (ROSC) following in/out-of-hospital cardiac arrest.
- Informed consent from patient or representative obtained before invasive coronary angiography.

7.2.2 Exclusion Criteria

- Patients on VA-ECMO
- ACS STEMI or STEMI "equivalent"
  - New left/right bundle branch block
  - ST segment depression in leads V1-V3, when the terminal T wave is positive and concomitant ST-segment elevation ≥ 0,5mm recorded in leads V7-V9 (posterior MI)
  - ST-segment elevation in V7-V9 (posterior MI) or V3R-V4R (RV MI)
- ACS NSTEMI with persistent ST depression despite optimal therapy, suggesting ongoing myocardial ischemia, with indication for an urgent ICA according to the treating physician.
- Hemodynamic/electrical instability precluding CT imaging (as perceived by the treating physician)
- Life-threatening arrhythmia potentially caused by acute myocardial ischemia
- Absolute contraindications to iodinated contrast
- Patients with a known non-cardiac cause of cardiac arrest (e.g., traumatic brain injury, overt hemorrhage, asphyxia/severe hypoxia due to known lung disease, trauma, severe

metabolic/electrolyte derangement, or intoxication) as perceived by the treating physician, where chest CT is considered unnecessary.
- Known or likely pregnancy or lactation
- Severe bleeding issue (as perceived by the treating physician) precluding heparin administration during radial access coronary angiography.
- Prior coronary intervention (stent implantation/CABG).
- CT findings indicating a condition that precludes coronary angiography in the short term.
- Patients with end-of-life care pathways.
- Participation in another intervention study interfering with the research questions in OPEN CCT Arrest.

7.2.3 Contraception / Pregnancy Avoidance Measures

Pregnant women will be excluded.

7.3 Study Duration for Subjects

90 days.

7.4 Group Allocation & Blinding (if applicable)

Not applicable.

8 Study Assessments and Procedures

8.1 Schedule of Activities

Chest CT scan (as early as possible) + CT brain (+ CT abdomen if perceived indicated by the treating physician) Pulmonary embolism/aortic dissection protocol ECG-less gated CCTA (1)	 Standard of care Study-specific
Invasive coronary angiography (<24 hours after CT scan)	Standard of care
Registration of baseline characteristics at admission (2)	Standard of care
Registration of study related parameters (3)	Study specific
Assessment of 90 days outcome (4)	Study-specific
Assessment of agreement between ECG-less CCTA and ICA (5)	Study-specific

ECG-less gated CCTA

ECG-less Cardiac software is an FDA-approved cardiac scan mode that acquires cardiac images without the need of a patient-attached ECG monitor. ECG-less Cardiac essentially utilizes existing CT system scan technology. The system uses a wide detector coverage of 160mm to provide full heart coverage and a fast gantry speed of 0.23 seconds per rotation to perform imaging in a single cardiac cycle. An estimate of the heart rhythm has to be provided, which is often readily available because emergency patients are already monitored. Based on the heart rhythm the scanner simulates an ECG signal. This simulated ECG signal provides virtual gating of the scan. The acquisition can be performed during a full heart cycle or three-quarters or half cycle, depending on how fast the heart rhythm is. The existing cardiac software options of SmartPhase (automated phase selection) and SnapShot Freeze 2 (optimized volume registration) amplify the quality of the images and correct for motion.

Patients are scanned using a Revolution Apex Elite system (GE Healthcare, Waukesha, WI -USA). We use a hyperdrive pulmonary CT angiography (523mm/s with 0.28s/rotation gantry speed). After a short delay of a few seconds (5-12 sec), allowing the contrast to leave the pulmonary circulation, and enter the aorta and coronary arteries, a coronary CT angiography is performed within the same contrast bolus. No extra contrast is given to acquire the cardiac images. No intravenous beta-blocker nor sublingual nitroglycerin is administered.
The total added exam time (assessing heart rhythm, preparing the scan parameters, the delay time and the acquisition itself) is about one to two minutes.
The dose-length product (DLP) of the ECG-less cardiac scan depends on the duration of the scan time that is chosen. The average DLP is between 150 and 200 mGy.cm. The diagnostic reference level (DRL) as set by the Federal Agency for Nuclear Controle (FANC) for a coronary CT angiography is 300 mGy.cm.

The combined pulmonary CT angiography and ECG-less cardiac scan can be used to diagnose all the pathologies that can be assessed on a conventional pulmonary CT angiography scan (including, but not limited to, pneumonia, pleural fluid, pulmonary embolism, pulmonary infarct, pulmonary mass, pneumothorax, pericardial fluid, etc.) and provides extra diagnostic information about coronary artery disease.

Baseline characteristics of the study population.
Age
Sex category
BMI
Medical conditions / cardiovascular risk factors
Diabetes mellitus
Arterial hypertension
Current smoker
Dyslipidemia
Peripheral artery disease
Previous stroke / Transient Ischemic Attack (TIA)
Clinical observations during cardiorespiratory arrest
Cardiac arrest witnessed
Shockable first monitored rhythm
Bystander CPR
No flow time
Low flow time
Median time from cardiac arrest to ROSC
After hospital admission
First arterial pH
First arterial lactate level
First troponin T level
First creatinine level
Vasoactive drug(s) (Y/N)

(1) Study related parameters

- Median time from cardiac arrest to ECG-less gated CCTA
- Median time from cardiac arrest to ICA
- Catheterization access
    - Femoral
    - Radial
    - Brachial
- Culprit lesion identified
- Patients with coronary artery disease without a culprit lesion
- Use of intravascular imaging (OCT/IVUS) (Y/N)
- PCI performed
- Median amount of contrast dye (CT scan)
- Median amount of contrast dye (coronary angiography)
- Total radiation dose (mSv)
- Time-to-diagnosis of ACS as a cause of cardiac arrest
- Time-to-diagnosis of a non-cardiac cause of cardiac arrest
    - Pulmonary embolism
    - Intracranial hemorrhage
    - Acute aortic dissection
    - Other
- Feasibility (patients meeting inclusion criteria where ECG-less CCTA with sufficient quality was obtained)

(2) Outcome at 90 days

- Survival (Y/N)
- severe neurologic deficit (≥ 3) (Y/N)
- Median peak troponin release
- Median length of ICU stay (days)
- Median duration of catecholamine support (days)
- Median peak SAPS II score
- Rehospitalization for heart failure (Y/N)
- Acute kidney injury (Y/N)
- Need for renal replacement therapy (Y/N)
- ISTH major bleeding event
- Ischemic stroke
- Need for mechanical circulatory support (MCS)
- Treatment with Dual Antiplatelet Therapy (DAPT)
- LV function on 90 days ambulatory follow-up visit

(3) Assessment of agreement between CCTA and ICA

Degree of coronary stenosis is divided into 3 categories (0, <50%, ≥50%) for every coronary segment. Angiographic and CT images are respectively evaluated by the consensus of two interventional cardiologists (ICA) and two interventional radiologists (CCTA), blinded for clinical data. In case of discrepant results between the two readers of the same imaging modality, a third reader will provide the deciding assessment.

The level of agreement will be assessed with the Weighted Kappa coefficient.

8.1.1 Screening

Screening will be performed by the treating physician in every cardiac arrest patient at the moment of ROSC.

8.1.2 Follow Up Period

Clinical data, mentioned above, will be collected at 90 days after inclusion by interrogation of the clinical data system (Primuz).

8.2 Detailed Study Assessments

8.2.1 Laboratory Testings

First arterial lactate and pH, venous creatinine and troponin T level.

8.2.2 Safety Assessments

Registration of contrast dye volume (for both CT and ICA), total radiation dose.

9 Interventions/Treatment

9.1 Treatments Administered

Standard of care for the treatment of cardiac arrest survivors will be administered.

9.2 Product/Device Characteristics

ECG-less Cardiac software is an FDA-approved cardiac scan mode that acquires cardiac images without the need of a patient-attached ECG monitor. ECG-less Cardiac essentially utilizes existing CT system scan technology. The system uses a wide detector coverage of 160mm to provide full heart coverage and a fast gantry speed of 0.23 seconds per rotation to perform imaging in a single cardiac cycle. An estimate of the heart rhythm has to be provided, which is often readily available because emergency patients are already monitored. Based on the heart rhythm the scanner simulates an ECG signal. This simulated ECG signal provides virtual gating of the scan. The acquisition can be performed during a full heart cycle or three-quarters or half cycle, depending on how fast the heart rhythm is. The existing cardiac software options of SmartPhase (automated phase selection) and SnapShot Freeze 2 (optimized volume registration) amplify the quality of the images and correct for motion.

Patients are scanned using a Revolution Apex Elite system (GE Healthcare, Waukesha, WI -USA). We use a hyperdrive pulmonary CT angiography (523mm/s with 0.28s/rotation gantry speed). After a short delay of a few seconds (5-12 sec), allowing the contrast to leave the pulmonary circulation, and enter the aorta and coronary arteries, a coronary CT angiography is performed within the same contrast bolus. No extra contrast is given to acquire the cardiac images. No intravenous beta-blocker nor sublingual nitroglycerin is administered.
The total added exam time (assessing heart rhythm, preparing the scan parameters, the delay time and the acquisition itself) is about one to two minutes. The dose-length product (DLP) of the ECG-less cardiac scan depends on the duration of the scan time that is chosen. The average DLP is between 150 and 200 mGy.cm. The diagnostic reference level (DRL) as set by the Federal Agency for Nuclear Control (FANC) for a coronary CT angiography is 300 mGy.cm.

The combined pulmonary CT angiography and ECG-less cardiac scan can be used to diagnose all the pathologies that can be assessed on a conventional pulmonary CT angiography scan (including, but not limited to, pneumonia, pleural fluid, pulmonary embolism, pulmonary infarct, pulmonary mass, pneumothorax, pericardial fluid, etc.) and provides extra diagnostic information about coronary artery disease.

10 Data Collection and Management

10.1 Monitoring

The investigator must make all trial documentation and related records available in case a monitoring visit is requested. Also in case of regulatory inspections all trial documentation should be made available to the inspector(s). All participant data must be handled and treated confidentially.

10.2 Data Collection

An Electronic Data Capture system "*RedCap*" will be used for data collection. Trial data will be entered within reasonable time after the subject underwent the necessary investigations. Corrections/modifications will be automatically tracked by an audit trail detailing date and time of the correction and the name of person performing the correction.

10.3 Database Management and Quality Control

Degree of coronary stenosis is divided into 3 categories (0, <50%, ≥50%) for every coronary segment. Angiographic and CT images are respectively evaluated by the consensus of two interventional cardiologists (ICA) and two interventional radiologists (CCTA), blinded for clinical data. In case of discrepant results between the two readers of the same imaging modality, a third reader will provide the deciding assessment.

The final conclusion on whether or not the cause of the cardiac arrest is related to the CAD, will be made by the interventional cardiologist performing the ICA, taking into account the clinical context, ECG findings, angiographic data and intracoronary imaging in case of doubt.

The level of agreement on the grade of coronary stenosis between CCTA and ICA will be assessed with the Weighted Kappa coefficient.

11 Safety Monitoring and Reporting

11.1 Adverse Events

11.1.1 Definitions

An adverse event is any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons in the context of a clinical investigation, whether or not related to the investigational device.

Note:

a) This definition includes events that are anticipated as well as unanticipated events
b) This definition includes events occurring in the context of a clinical investigation related to the investigational device, the comparator or the procedures involved

11.1.2 Reporting

Adverse events will be reported based on the analysis of the clinical patient file.

11.1.3 Laboratory Test Abnormalities

Follow-up of renal function will be documented.

11.2 Serious Adverse Events

11.2.1 Definitions

Any adverse event that led to any of the following:

a) Death,
b) Serious deterioration in the health of the subject, that resulted in any of the following:

- Life-threatening illness or injury,
- Permanent impairment of a body structure or a body function,
- Hospitalization or prolongation of patient hospitalization,
- Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment of a body structure or a body function,
- Chronic disease

c) Foetal distress, foetal death or a congenital physical or mental impairment or birth defect.

Medical and scientific judgement should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also be considered serious.

11.2.2 Immediate Reporting

11.3 Suspected Unexpected Serious Adverse Reactions (SUSAR)

11.3.1 Definitions

An adverse reaction is any untoward medical occurrence in a patient or clinical investigation subject participating in a clinical trial including any abnormal sign, symptom, or disease temporally associated with the participant's involvement in the research, whether or not considered to be related to the research.

Serious if:

- Results in death,
- Is life-threatening,
- Requires inpatient hospitalization or prolongation of existing hospitalization,
- Results in persistent or significant disability/incapacity,
- Is a congenital anomaly/birth defect

Or

- Other important medical condition (ICH 2EA)

Medical and scientific judgement should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also be considered serious.

11.4 Device Deficiencies

11.4.1 Definitions

Any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, user errors or inadequacy in information supplied by the manufacturer.

12 Ethical Considerations

12.1 Ethical Conduct of the Study

12.1.1 Declaration of Helsinki

The trial will be performed in accordance with the Declaration of Helsinki, the conditions and principles of Good Clinical Practice, the protocol and applicable local regulatory requirements and laws.

12.1.2 Ethics Committee

Before the start of the trial or implementation of any amendment, approval of the trial protocol and amendments, informed consent forms and other relevant documents will be obtained from the applicable ethical committee(s).

12.2 Recruitment and Informed Consent

Recruitment will be done by the treating physician at the moment of ROSC after cardiac arrest. Each participant or his/her representative shall provide Informed Consent before performance of the ICA. The IC form that is/are used must be approved by reviewing EC and be in a language that the participant can read and understand. The ICF should be in accordance with current ICH and GCP guidelines and with applicable local regulations.

12.3 Study Data Protection

The collection and processing of personal data from participants enrolled in the study will be limited to those data that are necessary to fulfill the objectives of this study. These data must be collected and processed with adequate precautions to ensure confidentiality and compliance with applicable data protection laws and regulations.

12.4 Subject Identification

The participant identification will be treated as confidential and will be filed by the investigator in an identification log. This log is kept at the participating site and shall not be copied. In all reports and communication the participant shall be identified with a participant study number.

13 Insurance

UZ Brussel/VUB is, as Sponsor of the trial, responsible for ensuring appropriate general/product liability insurance and as required in accordance with applicable laws and regulations, country-specific liability insurance coverage for claims made by a trial subjects for injury arising from the subject's participation in the trial.

14 Reporting and Dissemination

The data and information collected during this trial will be reported in a clinical trial report and/or a publication in a scientific/medical journal. Reporting of trial results will be performed according to local regulations.

For the correct authorship rules we refer to the International Committee of Medical Journal Editors: https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

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