Statistical Analysis Plan

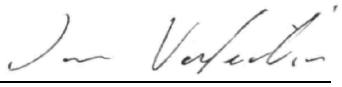
TRIAL FULL TITLE	Dispatch of Emergency Call Using Video Streaming Compared With Traditional Telephone Communication (CAM-VISION)
Clinical Trial Identifier	NCT05742412
Unique Protocol ID	3436
SAP VERSION	1
SAP VERSION DATE	18.08.2023
TRIAL STATISTICIAN	Jan Brink Valentin
TRIAL PRINCIPAL INVESTIGATOR	Martin Faurholdt Gude
SAP AUTHOR(s)	Martin Faurholdt Gude & Jan Brink Valentin

1. SAP Signatures

I give my approval for the attached SAP.

Statistician

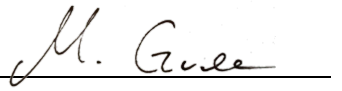
Name: Jan Brink Valentin

Signature: 

Date: 2023-08-27

Principal Investigator

Name: Martin Faurholdt Gude

Signature: 

Date: 27-08-2023

1.1 Table of Contents

2. Study Objectives and Endpoints

2.1 Study Objectives

To investigate differences in allocated urgency level when emergency calls are dispatched by emergency medical service (EMS) utilizing video streaming as opposed to sole telephone (audio-only) communication.

Secondary aims include the association between the use of video streaming and secondary and exploratory endpoints listed below.

2.2. Study period

The study will be conducted from January 1, 2023, to April 30, 2023.

2.3 Study setting and cluster design

In the Central Denmark Region, a single Emergency Medical Dispatch Center (EMDC) handles all emergency calls (equivalent to 9-1-1 calls in the US). The region receives approximately 55,000 to 60,000 emergency calls annually and employs around 25 Emergency Medical Service (EMS) Dispatchers, all of whom are either nurses or paramedics. Within the EMDC, EMS dispatchers were divided into one of two clusters, each containing 10 EMS dispatchers. Due to the limited number of clusters, a matched-pair (MP) design was adopted. This design relied on specific criteria for matching, including the average proportion of dispatched urgency levels (with the highest urgency level as the primary criterion), years of employment, and the average call duration. The data used for matching covered a 3-month period from January 1, 2022, to March 31, 2022, both prior to the introduction of video streaming and preceding the pilot phase of the study.

Newly employed personnel where matching was not possible were randomly assigned to one of the two clusters. Before the study period, the implementation of video streaming in the intervention group occurred progressively over a span of 7 months (from June 1, 2022, to December 31, 2022), following a pilot phase that took place from April 19, 2022, to May 31.

2.4 Endpoints

Primary Outcome Measure

- The frequency of dispatches with the highest level of urgency (A-responses)

Secondary Outcome Measures

- The frequency of dispatches with the levels of urgency A, B, C, D and E,
- Mortality within 30 days after study inclusion,
- Number of participants where the levels of urgency are identical when comparing the ambulance to and from the scene,

- Length of stay at hospital,
- The number of participants needing an ICU admission at hospital,
- Number of emergency calls where the dispatched level of urgency is changed during the call,
- Number of emergency calls where the initially dispatched level of urgency is subsequently lowered,
- Number of emergency calls where the initially dispatched level of urgency is subsequently increased,
- Number of emergency calls where the allocated resources is changed during the call,
- Number of participants readmitted to hospital within 24 hours after a dispatch without hospital admission (lowest level of urgency - response level E),
- Duration of emergency medical calls,
- Time from emergency call to dispatch,
- On-scene time

Other Pre-specified Outcome Measures:

- Number of participants with return-of-spontaneous circulation (ROSC) after cardiac arrest
- 90 days neurological outcome after cardiac arrest measured by the cerebral performance scale (CPC)
- 90 days functional outcome after cardiac arrest measured by the modified Rankin Scale (mRS)
- Number of patients with Stroke or TIA identified by the EMS dispatcher in the EMDC
- Rate of revascularization treatment (intravenous thrombolysis and/or endovascular treatment (EVT)) among patients with acute ischemic stroke
- Primary admission to a hospital offering acute stroke treatment
- Onset-to-treatment times for patients with acute ischemic stroke treated with i.v. thrombolysis and onset-to-groin-puncture for patients treated with EVT.
- Number of lowest level of urgency (response level E) dispatched among children (< 15 years of age)

- Re-admissions among children (< 15 years of age) to hospital within 24 hours from a prior emergency call dispatched with lowest level of urgency (response level E)
- Number of dispatches for each level of urgency (response level A, B, C, D and E) among children (< 15 years of age)

3 Study Methods

3.1 General Study Design and Plan

Study type: Single center, prospective, cluster-randomized, unblinded trial.

Type of Comparison: superiority

Type of control: Matched control group (matched-pair design)

Randomization: Emergency calls received in the Emergency Medical Dispatch Center are allocated randomly between the intervention group and the control group. Given the extended call duration within the intervention group, it is anticipated that the control group (telephone-only) will experience a higher volume of calls.

3.2 Inclusion-Exclusion Criteria and General Study Population

All emergency calls received at the Emergency Medical Dispatch Center and handled by either the intervention or control group will be included in the study.

Inclusion criteria

- Emergency calls (1-1-2 calls equivalent to 9-1-1 calls),
- Received by an EMS dispatcher included in the study (intervention or control group/cluster).

Exclusion criteria

- All calls to the EMDC other than emergency calls (including those from hospitals and general practitioners, including those outside of regular hours),
- Emergency calls managed by EMS dispatchers who are newly employed within the study period, on long-term leave, or not employed until the end of the study period are excluded from the study,

- Emergency calls managed by technical dispatchers (logistical dispatcher restricted to dispatching only the highest urgency level).

3.3 Randomization

Emergency calls will be allocated at random to either of the two clusters: the intervention group utilizing video, or the control group utilizing telephone-only communication. Alternatively, some emergency calls will be directed to EMS dispatchers who are not part of the study.

3.4 Sample Size

The CAM-VISION trial is conducted using a convenience sample, with an anticipated count of emergency calls during the study period ranging between 18,000 and 20,000.

3.5 Timing of Analyses

The study period and its corresponding follow-up periods, as determined by specific variables, are finalized during the drafting of this SAP (Statistical Analysis Plan).

As of this SAP, data extraction has not been initiated due to pending data authorization. The subsequent actions, in chronological order, prior to data extraction and analysis, are outlined below:

SAP Signature

- By the principal investigator and the senior statistician.

Data Authorization

- The Regional Research Council (The Legal Office, Central Denmark Region) and
- The Danish Data Protection Agency.

Primary Analyses

- Primary and Secondary Outcomes

Secondary analyses

- Other Outcomes

3.6 Analysis Populations

Intention to Treat (video stream)

The intention-to-treat populations (intension-to-video-stream) includes all patients allocated to either exposure group. Binary outcomes are investigated using risk differences (RD) implementing linear regression and relative risks (RR) by Poisson regression. Robust variance estimation is applied in both regression analyses. Continuous outcomes are investigated using linear and Tobit regression, where the latter is implemented for time variables that are right censored. Time-to-event variables are

investigated using Cox-regression analysis, while CPC and mRS are investigated using ordered logistic regression and by the concordance index. To account for cluster randomization, we will implement cluster robust variance in all regression analyses with a separate cluster id for each EMS dispatcher. Effect measures are presented with 95% confidence intervals and all analyses are conducted in Stata 17.

No per-protocol analyses will be conducted because of substantial risk of selection bias.

3.7 Missing Data

The anticipated connection between treatment allocation and loss to follow-up is expected to be minimal. Thus, missing data, including outcomes, is assumed to be missing at random and will be handled using multiple imputation.
The extent of missing data will be presented for outcome variables to quantify the degree of missing data.

3.8 Summary of Study Data

- Summary tables will be structured (columns for each cluster)
- Descriptive or summary statistics that will be displayed for continuous, categorical and binary data.

All continuous variables will be summarized as mean with standard deviation or median with interquartile range (25th and 75th percentiles) calculated based on the non-missing data. For categorical and binary measures, the frequency and percentages (calculated based on the non-missing sample size) will be provided.