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# Levosimendan in out of hospital cardiac arrest

**Submission date**
21/10/2025

**Recruitment status**
Not yet recruiting

**Registration date**
22/10/2025

**Overall study status**
Ongoing

**Last Edited**
06/02/2026

**Condition category**
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
Every year, around 6,000 people in Sweden suffer a cardiac arrest outside of hospital. Sadly, fewer than 1 in 10 survive to leave the hospital. While CPR and defibrillation can help restart the heart, medicines used during resuscitation have not shown much benefit in improving long-term survival. A drug called levosimendan, which helps the heart pump more effectively, has shown promise in early studies. This trial aims to find out whether giving levosimendan during CPR can improve survival 30 days after cardiac arrest. The results will help guide a larger future study focused on survival with good brain function.

Who can participate?
Adults aged 18 to 75 years who have a witnessed cardiac arrest outside of hospital may be eligible. To take part, CPR must begin quickly (within 2 minutes), and the heart rhythm must meet specific criteria. Patients must also have intravenous access. People will not be included if the cardiac arrest is caused by trauma, if the first heart rhythm is asystole, if the drug cannot be given within 30 minutes, or if they have certain serious health conditions or a Do Not Resuscitate order.

What does the study involve?
Eligible patients will be randomly assigned at the scene to receive either levosimendan or a placebo (a dummy treatment) during CPR. The study drug is given as a single dose. The medical team will continue standard resuscitation care. Researchers will then monitor outcomes such as survival, heart function, and neurological status.

What are the possible benefits and risks of participating?
The potential benefit is improved survival and heart function after cardiac arrest. Levosimendan has a good safety profile, but as with any medication, there may be risks or side effects. Because the drug is given during a medical emergency, patients cannot give consent beforehand. However, the study follows strict ethical guidelines to protect participants.

Where is the study run from?
The study is being conducted in the Stockholm region of Sweden.

When is the study starting and how long is it expected to run for?
June 2025 to July 2027

Who is funding the study?
The study is funded by Region Stockholm, the Swedish Heart and Lung Foundation, the Swedish Society for Medicine, and Karolinska Institutet.

who is the main contact?
Prof. Malin Jonsson Fagerlund, malin.jonsson-fagerlund@regionstockholm.se

# Contact information

### Type(s)
Public, Scientific, Principal investigator


### Contact name
Prof Malin Jonsson Fagerlund

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# Additional identifiers

### Clinical Trials Information System (CTIS)
2024-517279-20-02

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
Nil known

# Study information

### Scientific Title
Levosimendan in Cardiac Arrest: a randomized double-blinded clinical phase II trial (LeICA)

### Acronym
LeICA

### Study objectives
The primary objective of this trial is to investigate if a single dose of levosimendan given during cardiopulmonary resuscitation (CPR) for out-of-hospital cardiac arrest (OHCA) increases 30-day survival compared to placebo.

The secondary objective of this trial is to evaluate the clinical efficacy of levosimendan in comparison to placebo.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 11/06/2025, Swedish Medical Products Agency (PO Box 26, Uppsala, 75103, Sweden; + 46 (0)18 17 46 00; registrator@lakemedelsverket.se), ref: Dnr: 5.1.1-2025-025629

## Study design
Phase II investigator-initiated randomized parallel-group placebo-controlled double-blinded pilot trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Out-of-hospital cardiac arrest

## Interventions
The randomisation is done using an online randomisation tool.

The intervention is one intravenous bolus injection of levosimendan or placebo during ongoing prehospital CPR.

1. A prefilled, blinded, syringe with 50 ml of study drug: levosimendan 2.5 mg (2.5 mg/ml, 1 ml in 49 ml 5% glucose, total volume 50 ml)
2. A prefilled, blinded, syringe with 50 ml of placebo: 5% glucose (total volume 50 ml)

Standard monitoring and diagnostic equipment will be used according to present guidelines for cardiac arrest and ACL (for example defibrillator, external compressions with LUCAS).

The patients will be followed up in a specific CRF for 30 days and via hospital charts etc for 30 days.

## Intervention Type
Drug

## Phase
Phase II

## Drug/device/biological/vaccine name(s)
Levosimendan

## Primary outcome(s)
Survival at day 30 (binary) measured using patient records

### Key secondary outcome(s))
Measured using patient records:
1. Conversion to potentially perfusing rhythm (except VT) among patients without potentially perfusing rhythm at study start (binary)
2. Any ROSC (i.e. return of spontaneous pulse or blood pressure as determined by the treating clinician) (binary)
3. Transport to hospital (binary)
4. Survived event (i.e. ROSC sustained until arrival at the emergency department and transfer of care to medical staff at the receiving hospital) (binary)
5. Sustained ROSC (i.e. ≥20 min of uninterrupted spontaneous pulse or blood pressure as determined by the treating clinician) (binary)
6. Time to sustained ROSC (continuous, numerical)
7. Hospital arrival status (i.e. subject's condition at hospital arrival; ROSC, CPR in progress, deceased) (categorical)
8. Number and duration of vasopressor infusions (duration >1 h) in the ICU up to 72 hours (e.g. norepinephrine, epinephrine, phenylephrine, vasopressin, dopamine, methylene blue) (continuous)
9. Number and duration of inotrope infusions (duration >1 h) in the ICU up to 72 hours (e.g. epinephrine, dobutamine, milrinone, levosimendan) (continuous)
10. Mechanical circulatory support in the ICU within 7 days (e.g. veno-arterial extracorporeal membrane oxygenation [VA-ECMO], Impella device, intra-aortic balloon pump) (binary)
11. Organ dysfunction (e.g. renal, hepatic, cardiac) (exploratory)
12. Neurological outcome at discharge (i.e. cerebral performance category 1–2 or 3–5) (binary)
13. Circumstances of death (categorical)
14. Plasma concentration of levosimendan (during initial 72 hours in the intensive care unit) (continuous)
15. Organ donation (i.e. ≥1 solid organ donated for transplantation) (binary)

### Completion date
31/07/2027

## Eligibility

### Key inclusion criteria
1. Aged 18-75 years
2. Witnessed OHCA
3. Prompt start of CPR (i.e. within 2 minutes)
4. First recorded rhythm ventricular fibrillation (VF) or pulseless ventricular tachycardia (pVT), or pulseless electrical activity (PEA) in case of suspected pulmonary embolism (as determined by the attending physician)
5. Refractory cardiac arrest, i.e. sustained beyond third rhythm check
6. Intravenous access

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 years

### Upper age limit
75 years

### Sex
All

### Total final enrolment
0

### Key exclusion criteria
1. Traumatic cause of cardiac arrest
2. First recorded rhythm asystole
3. Time to administration of study drug >30 min after onset of cardiac arrest
4. Known or apparent pregnancy
5. Known pre-existing advanced malignancy, severe neurological or systemic disease, advanced cardiac or pulmonary disease, terminal chronic kidney disease on dialysis or ongoing bleeding
6. Known pre-existing (i.e. current) Do Not Attempt Cardiopulmonary Resuscitation (DNACPR) decision

### Date of first enrolment
25/02/2026

### Date of final enrolment
31/07/2026

## Locations

### Countries of recruitment
Sweden

### Study participating centre
**Karolinska University Hospital**
Eugeniavägen 3
Stockholm
Sweden
17176

### Study participating centre
**AISAB**
Box 90219
Stockholm
Sweden
12023

# Sponsor information

**Organisation**
Karolinska University Hospital

**ROR**
https://ror.org/00m8d6786

# Funder(s)

**Funder type**
Charity

**Funder Name**
Hjärt-Lungfonden

**Alternative Name(s)**
Swedish Heart-Lung Foundation

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
Sweden

**Funder Name**
Region Stockholm

**Funder Name**
Svenska Läkaresällskapet

**Alternative Name(s)**
Swedish Society of Medicine, Swedish Medical Society, SLS

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
Sweden

**Funder Name**
Karolinska Institutet

**Alternative Name(s)**
Karolinska Institute, KI

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Local government

**Location**
Sweden

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Data sharing statement to be made available at a later date

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | | 24/11/2025 | 25/11/2025 | Yes | No |