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Levosimendan in out of hospital cardiac arrest

Submission date 21/10/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 22/10/2025	**Overall study status** Ongoing	
Last Edited 21/09/2026	**Condition category** Circulatory System	

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 December 2028

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?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

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

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

Primary study design
Interventional

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

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
31/12/2028

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
14/04/2026

Date of final enrolment
31/12/2027

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, Hjart Lungfonden

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