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Dexmedetomidine to improve neurologic injury of patients after out-of-hospital cardiac arrest

Submission date 13/07/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 15/07/2026	**Overall study status** Ongoing	
Last Edited 14/07/2026	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific, Principal investigator, Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2026-527007-21-00

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FWF KLIF KLP2907025

Study information

Scientific Title

DEXmedetomidine to Improve Neurologic Injury of patients after out-of-hospital cardiac arrest – a phase II randomized, double blind, placebo-controlled, parallel group trial

Acronym
DEX-INI

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Basic science, Health services research, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Patients after out-of-hospital cardiac arrest

Interventions
Participants will be randomized in a 1:1 ratio to receive either dexmedetomidine or placebo. Randomization will be computer-generated using a centralized randomization schedule with stratification according to time to sustained circulation (≤30 minutes vs. >30 minutes) and the need for mechanical circulatory support (MCS). Allocation concealment will be ensured by identical study medication prepared by the hospital pharmacy, with investigators, treating clinicians, participants, outcome assessors, and data analysts remaining blinded throughout the study.

Intervention arm: Dexmedetomidine administered as a continuous intravenous infusion at 0.5 µg /kg/hour, initiated within 2 hours of hospital admission and continued for 24 hours, in addition to standard post-cardiac arrest care.

Control arm: Matching placebo (0.9% sodium chloride solution) administered as a continuous intravenous infusion with identical appearance, volume, and duration (24 hours), initiated within 2 hours of hospital admission, in addition to standard post-cardiac arrest care.

The active treatment period is 24 hours, followed by an observation period of 72 hours during hospitalization. Clinical follow-up assessments are performed at 30 days and 90 days after cardiac arrest to assess neurological outcome, survival, and quality of life.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Dexmedetomidine

Primary outcome(s)
1. Neurologic injury, assessed as the ranked composite endpoint of death before 72 hours and serum neuron-specific enolase (NSE) concentration; participants who die before 72 hours are assigned the worst outcome rank, measured using data collection and standard methods for a routine biomarker in the central laboratory at 72 hours after cardiac arrest

Key secondary outcome(s)
1. Neurological injury, assessed via serum neuron-specific enolase (NSE) concentration, measured using standard methods for a routine biomarker in the central laboratory at baseline, 6, 12, 24, 48 and 72 hours after cardiac arrest

2. Neurological injury, assessed via the ranked composite endpoint of death before 72 hours and serum S100β concentration; participants who die before 72 hours are assigned the worst outcome rank, measured using standard methods for a routine biomarker in the central laboratory at 72 hours after cardiac arrest

3. Neurological injury measured using serum S100β concentration measured using standard methods for a routine biomarker in the central laboratory at baseline, 6, 12, 24, 48 and 72 hours after cardiac arrest

4. Acute kidney injury, according to Kidney Disease: Improving Global Outcomes (KDIGO) criteria, measured using an assessment of serum creatinine and urine output, according to KDIGO criteria, from routine clinical data at the first 72 hours after cardiac arrest

5. Hypoxic liver injury, defined as a greater than 20-fold increase above the upper limit of normal for aspartate aminotransferase (AST) or alanine aminotransferase (ALT), measured using routine liver biochemistry and standard laboratory analysis at the first 72 hours after cardiac arrest

6. Cardiac injury, assessed via cardiac biomarkers (e.g. cardiac troponin T and creatine kinase) in participants with acute coronary syndrome, measured using standard methods for a routine biomarker in the central laboratory at baseline, 6, 12, 24, 48 and 72 hours after cardiac arrest

7. Inflammatory response, assessed via C-reactive protein (CRP), interleukin-6 (IL-6), and exploratory inflammatory biomarkers, measured using standard methods for a routine biomarker in the central laboratory at baseline, 6, 12, 24, 48 and 72 hours after cardiac arrest

8. Neurological functional outcome measured using the Cerebral Performance Category (CPC) scale at 30 and 90 days after cardiac arrest

9. Functional disability and all-cause mortality measured using clinical assessment using the modified Rankin Scale (mRS) and ascertainment of survival status at 30 and 90 days after cardiac arrest

10. Health-related quality of life measured using the EQ-5D-5L, EQ visual analogue scale (EQ VAS), Hospital Anxiety and Depression Scale (HADS), Short Form-36 (SF-36), and Barthel Index at 90 days after cardiac arrest

11. Safety, assessed via the frequency of adverse events, serious adverse events, and adverse events of special interest, including clinically relevant bradycardia and haemodynamic instability requiring intervention, measured using clinical assessment and safety monitoring throughout the study observation period at the end of the 72-hour observation period

Completion date
01/04/2029

Eligibility

Key inclusion criteria
1. Adult patients ≥ 18 years of age experiencing out-of-hospital cardiac arrest
2. Sustained ciruclation (defined as ROSC or successful eCPR flow lasting for at least 20 minutes) within 90 minutes of suspected collapse
3. Comatose (Glasgow Coma Scale <8) on admission or suspected in patients receiving sedatives
4. Start of the trial drug is possible within 2 hours of hospital admission
5. Subjected to temperature control
6. Combined no-flow and low-flow time of ≥ 10 minutes

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Expected death within 72 hours or expected survival to < 3 months
2. Known limitations to intesive care therapye and "Do Not Resuscitate" or "Allow Natural Death" orders
3. Advanced directive of patient to decline resuscitation, intensive care measures, or participation in a clinical trial according to the local legal requirements of participating trial sites
4. Known pre-arrest CPC of 3 or 4
5. Known diseases that may interfere with biomarkers indicative of neurological injury (e.g., cancer, inflammation, acute bleeding, stroke or infection of the central nervous system) at the discretion if the investigator
6. Time to sustained circulation > 90 minutes
7. No-flow time > 10 minutes
8. Unwitnessed cardiac arrest unless the no-flow time can safely be assumed to be < 10 minutes
9. Unmanageable hemodynamic and respiratory instability albeit the use of vasopressors and/or mechanical circulatory support - at the discretion of the treating physicians
10. Known allergies or inolerances against any of the substances used in the trial
11. Requirements of acute surgery at screening
12. Pregnancy or breastfeeding

Date of first enrolment
01/10/2026

Date of final enrolment
01/10/2028

Locations

Countries of recruitment
Austria

Sponsor information

Organisation
Medical University of Vienna

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type

Funder Name
Austrian Science Fund

Alternative Name(s)
FWF Austrian Science Fund, FWF Der Wissenschaftsfonds, Der Wissenschaftsfonds FWF, Österreichischer Wissenschaftsfonds, Fonds zur Förderung der Wissenschaftlichen Forschung, FWF, FFWF, FWF EN

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Austria

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	21/06/2026	13/07/2026	No	No
Statistical Analysis Plan	version 1.0	21/06/2026	13/07/2026	No	No