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Norepinephrine administration timing

Submission date 21/01/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 03/02/2026	**Overall study status** Ongoing	
Last Edited 20/10/2026	**Condition category** Infections and Infestations	

Plain English summary of protocol

Background and study aims
Sepsis is a life-threatening condition. Current clinical guidelines recommend norepinephrine (NE) as the primary treatment to increase blood pressure. However, it remains unclear exactly when this treatment should be initiated. Delayed treatment may lead to patients receiving excessive amounts of intravenous fluids, which can be harmful.

This study examines how quickly patients with sepsis receive NE in Sweden and the volume of fluids administered. We are studying patients at the emergency departments of four different hospitals. The goal is to determine if there is a correlation between the time to NE treatment and the amount of fluid given. The hypothesis is that patients who receive NE later also receive a larger volume of fluids.

Who can participate?
Patients who present to the emergency department in Swedish hospitals aged ≥ 18 years with suspected sepsis, defined as blood cultures obtained and intravenous antibiotics administered, and hypotension, defined as MAP < 65 mmHg.

What does the study involve?
This is an observational study. Participants are identified at the Emergency Department (ED) based on clinical criteria (suspected sepsis and hypotension). Data is collected prospectively using a paper Case Report Form (CRF) and supplemented with data from the participants' electronic medical records (EMR). Participation involves no changes to standard clinical care; the study only monitors and records the timing of interventions and fluid volumes as they occur in real-time or as documented in the medical records during the first 24 hours of care.

What are the possible benefits and risks of participating?
The results may indicate whether there is a need to adjust current clinical routines regarding the timing of sepsis treatment. This, in turn, could lead to improved patient care and a reduced risk of complications. The study does not affect the patients' treatment directly; instead, it gathers essential knowledge to improve healthcare in the future.

Where is the study run from?
Region Stockholm and the Karolinska Institute, Sweden.

When is the study starting and how long is it expected to run for?
February 2026 to December 2026.

Who is funding the study?
The ALF Agreement (Regional Agreement on Medical Training and Clinical Research) between the Swedish Government and Karolinska Institute, Sweden.

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
Time to norepinephrine in sepsis – a prospective inception cohort study

Acronym
NEAT

Study objectives
Rationale
If norepinephrine (NE) initiation is delayed and excessive fluids are administered during this period, it could necessitate a change in current Swedish clinical practice. This study aims to provide data on the time to NE initiation and fluid administration in adult patients with sepsis and hypotension in Sweden.

Objectives
1. To describe the use of NE in patients with sepsis in Swedish hospitals.
2. To describe the volume and type of fluids administered during the first 24 hours in Swedish hospitals.
3. Explore the association between amounts of fluids and the timing of NE initiation.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/06/2025, Swedish Ethical Review Authority (Box 2110, Uppsala, 75002, Sweden; +46 0104750800; registrator@etikprovning.se), ref: 2025-03002-01

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Sepsis with hypotension

Interventions
This is an observational study. Participants are identified at the Emergency Department (ED) based on clinical criteria (suspected sepsis and hypotension). Data is collected prospectively using a paper Case Report Form (CRF) and supplemented with data from the participants' electronic medical records (EMR). Participation involves no changes to standard clinical care; the study only monitors and records the timing of interventions and fluid volumes as they occur in real-time or as documented in the medical records during the first 24 hours of care.

Study design and setting
This is a prospective, multicenter cohort study involving emergency departments across Sweden. Patients will be enrolled over 28 days.

Number of subjects
The study aims to include approximately 204 patients who present to the emergency department in Swedish hospitals with sepsis and hypotension and where at least 61 subsequently receive NE.

Expected duration of the study
Each participating site will select 28 days for patient enrollment. Follow-up will continue for 90 days post-enrollment. The study is anticipated to commence on [Start Date] and conclude on [End Date].

Participants
All patients presenting to the emergency department at each site with suspected sepsis and hypotension will be screened for eligibility by local investigators.

Discontinuation of data collection
Data collection will go on for 24 hours.

Study closure
The study will end after the pre-planned number of participants has been enrolled.

Intervention Type
Other

Primary outcome(s)
1. Time from arrival at the Emergency Department (ED) to initiation of Norepinephrine (NE) infusion measured using data collected from the paper CRF (real-time documentation) and verified via electronic medical records (EMR) at one time point from ED admission until the start of NE infusion (within a maximum of 24 hours)

Key secondary outcome(s)
1. Total volume (mL) and types of resuscitation fluids administered measured using data collected from the paper CRF and EMR at the 24-hour time point following ED arrival

2. The association between the time of NE initiation and the total volume of fluids administered measured using data collected from the paper CRF and EMR for a statistical correlation analysis at the 24-hour time point

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Age ≥ 18 years
2. Suspected sepsis defined as, blood cultures obtained and intravenous antibiotics administered.
3. Hypotension defined as MAP < 65 mmHg.
4. eSOFA 2 points or more

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
189

Key exclusion criteria
Prior enrollment in this study.

Date of first enrolment
01/02/2026

Date of final enrolment
06/10/2026

Locations

Countries of recruitment
Sweden

Study participating centre
Danderyds sjukhus
Entrevägen 2
Stockholm
Sweden
18288

Study participating centre
Södersjukhuset
Sjukhusbacken 10
Stockholm
Sweden
11883

Study participating centre
Capio St Görans sjukhus
Sankt Göransplan 1
Stockholm
Sweden
11219

Study participating centre
Skaraborgs Sjukhus (SKAS)
Lövängsvägen 1
Skövde
Sweden
54949

Sponsor information

Organisation
Region Stockholm

Organisation
Karolinska Institutet

ROR
https://ror.org/056d84691

Funder(s)

Funder type

Funder Name
The ALF Agreement (Regional Agreement on Medical Training and Clinical Research) between the Swedish Government and Karolinska Institutet

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?
Participant information sheet			03/02/2026	No	Yes
Protocol file			22/01/2026	No	No

Statistical Analysis Plan	22/01/2026	No	No