

# Can repeated blood tests for heparin-binding protein concentration predict who will die from sepsis?

<b>Submission date</b> 08/10/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/12/2020	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/05/2021	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Sepsis is a leading cause of death and morbidity worldwide. Knowing early in the disease course who is at risk of not surviving could enable better care. With this study, we aim to investigate whether single or repeated measures of a blood test (Heparin-binding protein, HBP) can help prognosticate which patients will die from sepsis.

### Who can participate?

Patients who were already included in the FINNAKI study in Finland in 2011-2012.

### What does the study involve?

Blood tests and information from electronic health records.

### What are the possible benefits and risks of participating?

None.

### Where is the study run from?

Patient recruitment in Finland and blood sample and data analysis in Sweden.

### When is the study starting and how long is it expected to run for?

Recruitment was done in 2011-2012 and data analysis is planned for 2021.

### Who is funding the study?

In Finland: Juselius Foundation, Päivikki and Sakari Sohlberg Foundation, Helsinki University Hospital Grants.

In Sweden: Vetenskapsrådet (Swedish research council) and Swedish research grant (ALF).

### Who is the main contact?

Jonas Tverring, [jonas.tverring@med.lu.se](mailto:jonas.tverring@med.lu.se)

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Jonas Tverring

**ORCID ID**

<http://orcid.org/0000-0003-0939-6673>

**Contact details**

Sölvegatan 19, BMC, B14  
Division of Infection Medicine  
Department of Clinical Sciences  
Lund University  
Lund  
Sweden  
22184  
+46 (0)737677700  
[jonas.tverring@med.lu.se](mailto:jonas.tverring@med.lu.se)

## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

Nil known

## Study information

**Scientific Title**

Predicting 90-day survival in septic ICU patients: a post-hoc study of longitudinal heparin-binding protein measures from the FINNAKI cohort

**Study objectives**

Plasma HBP concentration adds predictive value to clinically available predictors regarding the number of days alive within 90 days from ICU admission (90-day survival) among patients with severe sepsis and septic shock when measured repeatedly during ICU stay (hour 0, 12, 24, 36, 48 hours, 3 days and 5 days from ICU admission, hereafter referred to as "longitudinal HBP" [ng/ml]).

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 17/03/2010, the Ethics Committee of the Department of Surgery, Helsinki and Uusimaa Hospital District (HUS Ethics Committees, PL 705, 00029 HUS Biomedicum Helsinki 2 C 7.krs, Tukholmankatu 8 C, Helsinki, Finland; +358 40 359 4618; eettiset.toimikunnat@hus.fi), ref: 18/13/03/02/2010

**Study design**

Exploratory post-hoc study of predictive biomarker performance using a cohort from a prospective observational multicentre study

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Diagnostic

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

**Health condition(s) or problem(s) studied**

Sepsis and septic shock

**Interventions**

The researchers will analyze HBP concentration on repeated plasma samples collected from patients in the FINNAKI study at 0, 12, 24, 36, 48, 72 and 120 hours from intensive care unit admission using a commercial HBP ELISA (Axis-Shield Diagnostics, Dundee, UK).

**Intervention Type**

Other

**Primary outcome measure**

Number of days alive within 90 days from intensive care unit admission measured using patient records

**Secondary outcome measures**

There are no secondary outcome measures

**Overall study start date**

06/11/2017

**Completion date**

18/06/2019

# Eligibility

## Key inclusion criteria

1. Patients included in the FINNAKI study, i.e. all emergency intensive care unit admissions aged >18 years and all elective patients aged >18 years with an intensive care unit stay longer than 24 h
2. Who had severe sepsis or septic shock diagnosed on the day of intensive care unit admission
3. Who had at least one plasma sample available from the first five days of ICU stay

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

652 (22%) out of a total 2901 patients included in the FINNAKI cohort

## Total final enrolment

652

## Key exclusion criteria

Exclusion criteria for the FINNAKI study:

1. End-stage renal disease requiring maintenance dialysis
2. Organ donors
3. Received intermediate care
4. Received renal replacement therapy (RRT) while enrolled in the study during a previous ICU admission
5. Transferred from another ICU where the data collection for the study was fulfilled
6. Not permanently living in Finland or unable to give consent due to insufficient language skills

## Date of first enrolment

01/09/2011

## Date of final enrolment

01/02/2012

# Locations

## Countries of recruitment

Finland

**Study participating centre**  
**Helsinki University Central Hospital**  
HUS Joint Authority  
Stenbäckinkatu 9  
PO Box 100  
Helsinki  
Finland  
00029

## **Sponsor information**

**Organisation**  
Lund University

**Sponsor details**  
Division of Infection Medicine  
Department of Clinical Sciences,  
Sölvegatan 19, BMC, B14  
Lund  
Sweden  
22184  
+46 (0)462220000  
lu@lu.se

**Sponsor type**  
University/education

**Website**  
<https://www.lunduniversity.lu.se/lucat/group/v1000442>

**ROR**  
<https://ror.org/012a77v79>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Swedish Government Research Grant (ALF)

**Funder Name**

Stiftelsen Thelma Zoégas fond för medicinsk forskning (91282)

**Alternative Name(s)**

The Thelma Zoéga Foundation for Medical Research

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Sweden

**Funder Name**

Vetenskapsrådet

**Alternative Name(s)**

Swedish Research Council, VR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Sweden

**Funder Name**

Axis-Shield Diagnostics (UK)

## Results and Publications

**Publication and dissemination plan**

The researchers intend to publish a manuscript in a peer-reviewed medical journal in 2021.

**Intention to publish date**

01/11/2021

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

## IPD sharing plan summary

Available on request

### Study outputs

Output type

[Statistical Analysis Plan](#)

Details

Date created

29/10/2020

Date added

03/12/2020

Peer reviewed?

No

Patient-facing?

No