ISRCTN15560762 https://doi.org/10.1186/ISRCTN15560762

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

Submission date
08/10/2020

Recruitment status
No longer recruiting

Registration date
03/12/2020

Overall study status
Completed

Last Edited
12/05/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Diagnostic

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

Key secondary outcome(s))
There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

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

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

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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan		29/10/2020	03/12/2020	No	No