Technical validation of transport and temperature stability at room temperature of presepsin measured with Elecsys® Presepsin.

Published: 06-01-2025
Last updated: 18-01-2025

The objective of this pilot study is to assess whether transportation of the sample via a pneumatic tube system (PTS) has any detrimental effects on the recovery of presepsin levels, when compared to traditional hand-delivery. This research will be...

Ethical review	Approved WMO
Status	Pending
Health condition type	Infections - pathogen unspecified
Study type	Observational invasive

Summary

ID

NL-OMON57218

Source
ToetsingOnline

Brief title
Presepsin pilot study

Condition

- Infections - pathogen unspecified

Synonym
infection, sepsis

Research involving
Human

Sponsors and support

Primary sponsor: Roche Diagnostics GmbH

Source(s) of monetary or material Support: Roche Diagnostics GmbH

Intervention

Keyword: Presepsin, Stability, Temperature, Transport

Outcome measures

Primary outcome

The slope of the linear regression line of the presepsin concentrations measured after the two transport methods should be within a clinically reasonable range (slope 1.00 ± 0.15, and/or the correlation (Pearson*s r) > 0.900). After evaluating the results of the first 45 samples (equally distributed between the three concentration ranges), if the outcome is negatively conclusive, the study can stop, otherwise the collection of samples shall continue until up to 130 results approximately equally distributed between the given sample ranges are reached. Due to the desire for an even distribution, a maximum of 200 subjects are included.

Secondary outcome

The measured concentrations of presepsin immediately after arrival are compared with the measured concentrations of presepsin at two time points the next day. This determines the stability at room temperature.

Stability is determined by:

Absolute deviation: recovery concentration Presepsin <= 500 pg/mL: +/- 50 pg/mL

Relative deviation: Presepsin > 500: +/- 10%

Study description

Background summary

The Elecsys® Presepsin assay is an immunoassay utilizing the electrochemiluminescence »ECLIA« technology for the quantitative in vitro measurement of presepsin in human serum and plasma. The test uses two monoclonal antibodies specifically directed against presepsin.
This study is being conducted to obtain information on transport and temperature stability at room temperature as part of the technical validation to be able to obtain future approval for use of Elecsys® Presepsin in clinical practice by the regulatory authorities.

Study objective

The objective of this pilot study is to assess whether transportation of the sample via a pneumatic tube system (PTS) has any detrimental effects on the recovery of presepsin levels, when compared to traditional hand-delivery. This research will be carried out in three types of materials (serum, heparin plasma and EDTA plasma), of each type two tubes will be collected.
The secondary (optional) objective is to test the room temperature stability of presepsin.

Study design

Prospective, non-interventional, observational, multicenter study enrolling patients with no, beginning or clear signs of infection/sepsis.

Study burden and risks

The burden amounts to taking a maximum of 2x 30 ml during two planned bloodwithdrawls during regular care. The only risks of the study are the possible side effects of a venipunture.

Contacts

Public
Roche Diagnostics GmbH

Sandhofer Strasse 116
Mannheim 63805
DE

Scientific
Roche Diagnostics GmbH

Sandhofer Strasse 116
Mannheim 63805
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Signed Informed Consent
Age >= 18 years

To obtain higher concentrations of presepsin: characteristics of infection, high CRP or PCT values in plasma.

Exclusion criteria

Self-declared pregnancy or breast-feeding women.
Dependent of sponsor or investigator.
Known/self-declared anemia.
Cognitive impairment.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-11-2024
Enrollment:	200
Type:	Anticipated

Medical products/devices used

Generic name:	Elecsys Presepsin
Registration:	No

Ethics review

Approved WMO

Date:	06-01-2025
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL87568.000.24