Exploratory study to investigate the association between the onset of disseminated intravascular coagulation (DIC) and disease progression with different biomarker candidates as well as standard clinical and demographic parameters in adult patients with sepsis.

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The primary purpose of this study is to enhance the understanding of the disease progression in sepsis, particularly from ICU admission to the development of DIC. This will be achieved by investigating the association between various biomarkers with...

Ethical review	Approved WMO
Status	Pending
Health condition type	Ancillary infectious topics
Study type	Observational invasive

Summary

ID

NL-OMON57271

Source
ToetsingOnline

Brief title
Study on DIC and disease progression in sepsis patients

Condition

- Ancillary infectious topics

Synonym
Sepsis; blood poisoning. Coagulopathy; bleeding disorder.

Research involving
Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: Bayer AG

Intervention

Keyword: biomarkers, disseminated intravascular coagulation (DIC), exploratory study, sepsis

Outcome measures

Primary outcome

Primary objective: Quantification and assessment of the association of

(combinations of) biomarkers and standard clinical and demographic

characteristics with the (non-) occurrence of DIC. Both baseline levels as well

as the longitudinal development of such markers will be of interest.

Primary endpoint: Occurrence of DIC as defined by ISTH criteria.

Secondary outcome

Secondary objective: Quantification and assessment of the association of

(combinations of) biomarkers and standard clinical and demographic

characteristics with a range of ICU related clinical endpoints. Both baseline

levels as well as the longitudinal development of such markers will be of

interest.

Secondary endpoints:

• SOFA score at baseline

• SOFA score (change from baseline on Day 5 or End of ICU stay, whichever

happens first)

• All-cause mortality until Day 56

• Organ support status until Day 56

• Hospitalization status until Day 56

Study description

Background summary

Septic DIC is a complex condition characterized by systemic activation of blood coagulation, leading to microvascular thrombosis and consumption of clotting factors and platelets. This condition is caused by a strong inflammatory response to infections, usually bacterial, which releases pro-inflammatory cytokines that activate the coagulation cascade. This results in an imbalance between pro-coagulant and anti-coagulant factors, leading to the formation of microthrombi and an increased risk of bleeding. The current treatment focuses on addressing the underlying infection and supporting organ function, but there are significant medical needs due to the complexity and severity of the condition.

Study objective

The primary purpose of this study is to enhance the understanding of the disease progression in sepsis, particularly from ICU admission to the development of DIC. This will be achieved by investigating the association between various biomarkers with respect to underlying molecular pathways and mechanisms and standard clinical and demographic parameters with the occurrence and progression of DIC.

Study design

This is an exploratory study in patients with sepsis. No study drug application is planned. The assumed study duration is 15 months.

Study burden and risks

The risks associated with this study are primarily related to the collection of blood samples, but these do not significantly interfere with standard care. Blood collection usually occurs simultaneously with regular clinical

examinations, which means there are no additional procedural risks. Participants will not personally benefit from the study; the aim is to enhance the understanding of the molecular pathophysiology of DIC in sepsis and to identify biomarkers. The benefits of the study, such as improving the early identification of at-risk patients and developing new therapeutic strategies, outweigh the manageable risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Participant must be 18 years of age inclusive, at the time of signing the informed consent.
2. Participants with diagnosed sepsis according to sepsis-3 definition.

3. Participants with documented suspected origin of infection.

Exclusion criteria

1. Patients deferred from other ICUs
2. Patients longer than 24 hours on ICU
3. Known coagulation disorder
4. Ongoing active clinically significant bleeding
5. Participants experienced trauma or major surgery (within 4 weeks)
6. Active malignancy
7. Decompensated liver impairment Child-Pugh Class C
8. Moribund patients not expected to survive 24 hours (clinical decision)
9. Ongoing therapeutic anticoagulation (prophylactic dose of UFH/LMWH is allowed) or antiplatelet therapy (except low dose [<=100 mg] acetyl salicylic acid [ASA]). If previously named treatment can be stopped the participants will be eligible if a *wash out *-time of five half-lives is applied before start of study.

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):	06-01-2025
Enrollment:	18
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	23-01-2025
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL87949.091.24