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Improving diagnosis of severe soft tissue infections in the emergency room

Submission date
14/10/2025

Recruitment status
Recruiting

Registration date
17/10/2025

Overall study status
Ongoing

Last Edited
15/10/2025

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Skin and soft tissue infections are diseases that affect the skin, muscles, and connective tissue. These infections are commonly caused by bacteria. Mild and moderate infections, such as impetigo or erysipelas, are typically treated with antibiotics and home care. However, other infections can lead to serious complications and require hospitalization. The most severe soft tissue infections cause cell death (NSTI: Necrotizing Soft Tissue Infections). NSTI is a life-threatening infection that requires surgery for accurate diagnosis and treatment. NSTIs progress rapidly and can, within hours, cause extensive tissue damage and complications such as circulatory failure and the failure of critical body functions. Early diagnosis is crucial to save lives and prevent amputation. Immediate surgery is recommended and necessary to improve prognosis in NSTI, but it also leads to unnecessary acute surgeries in patients with soft tissue infections without cell death (non-NSTI). In previous studies, the concentration of thrombomodulin (sTM) in the blood was a promising biomarker for distinguishing NSTI from non-NSTI. These studies were conducted on patients who were cared for in the intensive care unit. However, the potential of thrombomodulin early in the disease process is still unknown. This study aims to evaluate thrombomodulin and other proteins as early biomarkers for severe soft tissue infections, etiology and severity in the emergency department.

Who can participate?

Adult patients with severe soft tissue infections will be enrolled at the emergency departments of Danderyds Hospital, Karolinska University Hospital Huddinge, and Södersjukhuset in Region Stockholm.

What does the study involve?

Upon admission, blood samples will be drawn from patients with suspected NSTI in the emergency ward. The samples will be stored in a Biobank. The concentration of thrombomodulin and other biomarkers will be measured and the levels from patients with confirmed necrotizing soft tissue infection (NSTI) based on surgical findings will be compared to those from patients with non-NSTI. We will also explore other biomarkers for etiology of infection and severity of disease.

What are the possible benefits and risks of participating?
Participants in this study will not receive any direct benefit from the results. However, the knowledge we gain may help doctors and nurses become more aware of this condition and how important it is to act quickly. In the future, this could help improve care for others with the same condition – and possibly benefit the participants themselves if they were to face a similar situation again.

This is an observational study, which means it will not affect the medical care participants receive in any way. There are no physical risks involved, other than a small blood sample being taken. While blood tests can sometimes feel uncomfortable and may cause a small bruise, they are not dangerous. As the samples need to be collected early in the illness, and as severe soft tissue infection affects mental capacity, the participants will receive full study information after they have recovered. We will make sure to clearly explain the study when participants are well enough, and we will emphasize that taking part is completely voluntary.

Where is the study run from?
Patients will be enrolled at the emergency departments of Danderyds Hospital, Karolinska University Hospital Huddinge, and Södersjukhuset in Region Stockholm (Sweden).

When is the study starting and how long is it expected to run for.
The study is planned to start in October 2025 and is planned to enrol patients during a period of about 3 years.

Who is funding the study?
1. The Swedish Sepsis Trust
2. The Clas Groschinsky Memorial Foundation
3. KI Foundations Grant
4. Åke Wiberg Foundation
5. The Center for Innovative Medicine (CIMED)

Who is the main contact?
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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Region Stockholm Clinical Trials 4557

Study information

Scientific Title

Biomarker-based diagnosis of severe soft tissue infections in the emergency room

Acronym
BioSTER

Study objectives
Rapid diagnosis and treatment of necrotizing soft tissue infection (NSTI) is crucial, but early diagnosis can be challenging. A previous study conducted on plasma samples from patients with severe soft tissue infections treated in the Intensive Care Unit (ICU) identified Thrombomodulin as a potential biomarker. Thrombomodulin robustly identified NSTI cases versus those with suspected NSTI where no necrosis was detected during surgical exploration (non-NSTI). This previous study analyzed samples collected at the ICU of specialized hospital. This study aims to assess the accuracy of Thrombomodulin and other proteins as early biomarkers facilitating the diagnosis of severe soft tissue infections, including NSTIs, in the emergency department. We will also explore other biomarkers for etiology of infection and the severity of disease.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/05/2025, Swedish Ethical Review Authority (Box 2110, Uppsala, 75002, Sweden; +4610-475 08 00; registrator@etikprovning.se), ref: 2025-01223-01

Study design
Multicenter observational study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Prospective validation of the diagnostic potential of biomarkers for severe soft tissue infections in the emergency ward

Interventions
Blood samples will be drawn in the emergency ward. The patients will be informed about the study and asked for consent during their hospital stay. Health data from the hospital stay will be gathered from each participant’s medical record. The blood samples will be stored in a biobank.

Intervention Type
Other

Primary outcome(s)
The accuracy of Thrombomodulin as a diagnostic marker for NSTI assessed by AUC, sensitivity, and specificity. Thrombomodulin concentration will be measured on samples taken at admission to the emergency department and analysed with standard techniques such as ELISA and/or CLIA. Thrombomodulin concentrations will be compared between patients with and without NSTI, based on exploratory surgery findings.

Key secondary outcome(s))
The accuracy of a panel of plasma biomarkers in detecting aetiology and risk of severe disease in patients with severe soft tissue infections assessed by AUC, sensitivity, and specificity. Protein concentrations will be measured on samples taken at admission to the emergency department, and analysed with standard techniques such as ELISA, CLIA and/or Multiplex Luminex. Biomarker concentrations will be compared across patients with varying disease severity and different bacterial sources of infection

Completion date
31/10/2028

Eligibility

Key inclusion criteria
Adult patients (≥18 years) in the emergency ward where there is clinical suspicion of necrotizing soft tissue infection with at least one of the following symptoms and signs:
1. Disproportionate pain
2. Rapid spreading of redness, swelling/induration or blisters
3. Hypotension with a mean arterial pressure of less than 65 mmHg
4. Clinical suspicion by the attending physician prompting a consult with orthopaedics or an infection specialist

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
130 years

Sex
All

Key exclusion criteria
The patient doesn't want to participate in the study

Date of first enrolment
20/10/2025

Date of final enrolment
31/03/2028

Locations

Countries of recruitment
Sweden

Study participating centre
Danderyd Hospital
Entrévägen 2
Danderyd
Sweden
182 88

Study participating centre
Karolinska University Hospital Huddinge
Hälsovägen 13
Huddinge
Sweden
141 57

Study participating centre
Södersjukhuset
Sjukhusbacken 10
Stockholm
Sweden
118 83

Sponsor information

Organisation
Region Stockholm

Funder(s)

Funder type
Research organisation

Funder Name
Swedish Sepsis Trust

Funder Name
Stiftelsen Clas Groschinskys Minnesfond

Alternative Name(s)
Clas Groschinski's Memorial Foundation, Clas Groschinski Memorial Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Funder Name
KI Foundations Grant

Funder Name
Åke Wiberg Foundation

Funder Name
Center for Innovative Medicine

Alternative Name(s)
CIMED

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from maria.cronhjort@regionstockholm.se

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes