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How to quickly determine the severity of an infectious disease from a complete blood count?

Submission date
04/10/2023

Recruitment status
No longer recruiting

Registration date
07/11/2023

Overall study status
Completed

Last Edited
18/10/2024

Condition category
Haematological Disorders

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

Plain English summary of protocol

Background and study aims
Sepsis is a serious problem in hospitals, and it's the main reason why some patients don't make it. It affects a lot of people and makes them sicker, leading to more deaths and expensive medical bills. The ways doctors currently use to find out if someone has sepsis are not perfect. So, new methods are required that can tell us if someone might get sepsis earlier. This is important because when it is known earlier, treatment can be started sooner to give the patient a better chance of getting better. A recent study in emergency rooms found that looking at a certain type of blood cell, called a monocyte, can help. If there's a big change in the number of these cells in your blood, it might mean you have sepsis. They found that if the number goes up by more than 20.0 units, it is a good sign that someone might have sepsis or be at risk of getting it. Right now, this test called the monocyte distribution width (MDW) can be done as part of a regular blood test, and it's not too expensive or slow. So, it could be a really useful tool to spot sepsis early and start treatment as soon as possible.

Who can participate?
All adults who go to the emergency department and are later admitted to the hospital (either to the regular medical ward or the intensive care unit), and whose doctors order a complete blood count with differential when they first arrive, will be part of this study.

What does the study involve?
This is a non-interventional cohort study. MDW results will be unavailable to the physicians in charge and subjects were not managed based on the results of MDW. All routine clinical and paraclinical data will be recorded in and extracted from a hospital's electronic medical records.

What are the possible benefits and risks of participating?
None. The study does not require any additional blood draws or procedures that would not already have been performed as part of their standard medical care.

Where is the study run from?
Beckman Coulter (Czech Republic)

When is the study starting and how long is it expected to run for?
August 2020 to December 2022

Who is funding the study?
Faculty of Medicine in Pilsen (Czech Republic)

Who is the main contact?
Prof. MUDr. Martin Matějovič, Ph.D., matejovic@fnplzen.cz

Contact information

Type(s)
Scientific, Principal investigator

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
393/2020

Study information

Scientific Title
Evaluation of monocyte distribution width for early detection of sepsis

Study objectives
Monocyte distribution width (MDW) provides superior/additional diagnostic value for early detection of life-threatening infections and sepsis as compared to already available from established clinical assessments and laboratory investigations.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 06/08/2020, Ethic committee University Hospital and Faculty of Medicine, Charles University Pilsen (Edvarda Beneše 13, Pilsen, 30599, Czech Republic; +420 377402239; suchyd@fnplzen.cz), ref: 343/2020

Study design
Observational exploratory prospective non-interventional cohort study in single-center high-volume academic center

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Evaluation of monocyte distribution width for early detection of sepsis

Interventions
This is a non-interventional cohort study. Monocyte distribution width (MDW) results will be unavailable to the physicians in charge and subjects will not be managed based on the results of MDW. All routine clinical and paraclinical data will be recorded and extracted from a hospital's electronic medical records. The total duration of observation is from the time of hospital admission to the time of hospital discharge.

Intervention Type
Other

Primary outcome(s)
The following primary outcome measures are assessed using medical records and blood collected at the time of the emergency department visit:
1. Diagnostic performance of monocyte distribution width (MDW) in adult patients with community-acquired uncomplicated infections, sepsis and septic shock measured using a UniCelDxH 900 analyzer (Beckman Coulter, Inc., Brea, CA) using blood collected at the time of

the emergency department visit
2. C-reactive protein measured using standard methods in all patients
3. Procalcitonin measured using standard methods when clinically indicated

Key secondary outcome(s))
The following secondary outcome measures are measured using medical records and blood collected at the time of the emergency department visit:
1. Sources of heterogeneity in the estimates of diagnostic accuracy (e.g. immunosuppression, cancer, autoimmunity, chronic comorbidities, etc.)
2. The influence of different types of pathogens (e.g. gram-positive, gram-negative, fungal, viral) and sites of infection on MDW
3. Diagnostic accuracy of MDW in the distinction of sepsis from non-infectious conditions

Completion date
31/12/2022

Eligibility

Key inclusion criteria
All consecutive adults presenting to the Emergency department and subsequently admitted to the hospital (medical ward or intensive care unit) and for whom complete blood count with differential is ordered upon presentation will be included into the study. Patients will be categorized into several pre-defined groups:
1. Patients with and without infections regardless the presence of SIRS criteria;
2. Patients with definitive diagnosis of infection or sepsis (defined according to Sepsis-3 criteria) will further be subdivided in clinically documented infection/sepsis and microbiologically documented infection/sepsis;
3. Microbiologically documented infection/sepsis will further be subdivided into bacterial and non-bacterial infections depending on the type of germ cultured or identified otherwise (PCR etc.);
4. Patients with infection will be compared to patients fulfilling criteria for sepsis or septic shock;
5. Patients will also be categorized into infected-SIRS and non-infected SIRS groups and analyzed separately.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex

All

Total final enrolment
1925

Key exclusion criteria
1. Previously enrolled in this study (i.e. subjects may not be enrolled more than once in this study)
2. Subjects discharged from the ED
3. Subjects with CRP and PCT not performed
4. Pregnant women
5. Relevant limitations of therapy

Date of first enrolment
01/09/2020

Date of final enrolment
31/10/2020

Locations

Countries of recruitment
Czech Republic

Study participating centre
University Hospital Pilsen
Edvarda Beneše 1128/13
Pilsen
Czech Republic
30100

Sponsor information

Organisation
Beckman Coulter

Funder(s)

Funder type
University/education

Funder Name

Lékařská Fakulta v Plzni, Univerzita Karlova

Alternative Name(s)
Faculty of Medicine in Pilsen, Charles University

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Czech Republic

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 upon reasonable request, Prof. MUDr. Martin Matějovič, Ph.D., matejovic@fnplzen.cz.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/07/2024	18/10/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes