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Bleeding complications after cardiac treatment

Submission date 01/01/2024	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 05/01/2024	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 05/01/2024	**Condition category** Circulatory System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The project assumes broadening of knowledge among patients hospitalized in non-cardiac departments who receive treatment that increases the risk of bleeding, determining the factors affecting this risk and optimizing the diagnostic and therapeutic process among these patients.

There are currently no extensive analyzes of bleeding complications in non-cardiology departments, the publications that will be created on the basis of the collected database will supplement the missing knowledge in the field of planning anticoagulant and/or antiplatelet treatment and management of complications of the above therapy. The endpoints can also be used to create guidelines and various expert positions.

Who can participate?
Patients receiving anticoagulant and/or antiplatelet therapy hospitalized in non-cardiac departments with a complication of treatment in the form of bleeding.

What does the study involve?
Our study is a prospective, multicenter, registry study. We plan to invite several centers to the register, including several departments with different profiles - including surgical and non-surgical ones (neurology, urology, gastroenterology, surgery, otolaryngology, gynecology etc.) We are focusing on patients who are receiving antiplatelet and/or anticoagulant therapy with bleeding complications. The study population will be characterized according to the type of received treatment and also the type of bleeding. We plan to collect data for about 2 years with 1 month and 1 year follow-up after hospitalization.

What are the possible benefits and risks of participating?
None

Where is the study run from?
MezzoCardio (Poland)

When is the study starting and how long is it expected to run for?
September 2021 to December 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
BLEEDing complications After Cardiac Treatment - BLEED-ACT Registry

Acronym
BLEED-ACT

Study objectives

The project assumes broadening of knowledge among patients hospitalized in non-cardiac departments who receive treatment that increases the risk of bleeding, determining the factors affecting this risk and optimizing the diagnostic and therapeutic process among these patients.

Ethics approval required
Ethics approval not required

Ethics approval(s)
Our trial is a study of patient data, not an experiment so it does not require an ethics approval. We have received an opinion of the bioethical committee on this matter - no. PCN/CBN/0022/KB /239/21

Study design
Multicenter registry study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Home, Hospital, Laboratory, Medical and other records, Telephone

Study type(s)
Diagnostic, Prevention, Quality of life, Screening, Treatment, Safety, Efficacy

Participant information sheet
To follow

Health condition(s) or problem(s) studied
Patients who are receiving antiplatelet and/or anticoagulant therapy with bleeding complications.

Interventions
Our study is a prospective, multicenter, registry study. We plan to invite several centers to the register, including several departments with different profiles - including surgical and non-surgical ones.
We will collect data on risk factors, etiology, diagnostics, management and prognosis in patients with bleeding complications.
Data will be collected for 24 months with one year of prospective observation. Patients over 18 years of age will be eligible for the study.
Exclusion criterion - lack of consent to participate in the register.

Intervention Type
Other

Primary outcome measure
Basic clinical data on risk factors collected upon admission to hospital, upon discharge and one month after hospitalization:

1. Cardiovascular risk
2. Risk of bleeding
3. Thrombosis
4. Multi-morbidity
5. Indications and method of cardiac treatment (antiplatelet/anticoagulation)
6. Management of a patient undergoing cardiological treatment under planned conditions in the surgical ward
7. Leading symptoms of bleeding, location and degree of bleeding assessed based on the international BARC scale
8. In-hospital diagnostics
9. Management of bleeding
10. Length of hospitalization
11. Possible change of cardiac treatment after bleeding and prognosis in patients with bleeding complications

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/09/2021

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Age over 18 years
2. Gender – women and men
3. Patients receiving anticoagulant and/or antiplatelet therapy hospitalized in non-cardiac departments with a complication of treatment in the form of bleeding.

Participant type(s)
Patient, Population

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1000

Key exclusion criteria
1. Age under 18 years of age
2. Lack of consent to participate in the register

Date of first enrolment
01/01/2024

Date of final enrolment
30/11/2025

Locations

Countries of recruitment
Poland

Study participating centre
II Department of Cardiology, School of Medicine with the Division of Dentistry in Zabrze, Medical University of Katowice
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Sponsor information

Organisation
MezzoCardio

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Sponsor type
Other

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication