

Bleeding complications after cardiac treatment

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
01/01/2024	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
05/01/2024	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
05/01/2024	Circulatory System	<input type="checkbox"/> 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?
Dr Maciej Kocjan, maciej.kocjan@sum.edu.pl
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)

Diagnostic, Prevention, Quality of life, Screening, Treatment, Safety, Efficacy

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(s)

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

Key secondary outcome(s)

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Sklodowskiej-Curie 10
Zabrze
Poland
41-800

Sponsor information

Organisation
MezzoCardio

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

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