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# Bleeding complications after cardiac treatment

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| **Submission date**<br>01/01/2024 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>05/01/2024 | **Overall study status**<br>Ongoing | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>05/01/2024 | **Condition category**<br>Circulatory System | [_] Individual participant data<br>[_] 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
Prof Damian Kawecki, damian.kawecki@sum.edu.pl

# Contact information

### Type(s)
Public, Scientific, Principal investigator

### Contact name
Prof Damian Kawecki

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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 |