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Comparing two ways to remove blood clots from the lungs: how different catheter sizes affect heart recovery and patient outcomes in serious pulmonary embolism

Submission date 23/08/2025	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 05/09/2025	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 05/09/2025	**Condition category** Circulatory System	[ ] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Pulmonary embolism (PE) is a serious condition caused by blood clots blocking arteries in the lungs. These clots often come from the legs and can lead to death or long-term problems like difficulty breathing during everyday activities. This study looks at two different types of catheters (thin tubes used in treatment) to remove clots from the lungs. One is a standard-size catheter, and the other is a larger one that might work better for bigger or older clots. The aim is to find out which catheter is more effective and safer for patients with a type of PE called "submassive PE."

Who can participate?
Adults aged 18 to 74 who have submassive PE and meet certain medical criteria may be eligible. Participation depends on the availability of the large-bore catheter system at the hospital.

What does the study involve?
Participants receive treatment using either a standard-size catheter or a large-bore catheter to remove blood clots from their lungs. The type of catheter used is based on what is available at the time—not on the doctor's or patient's choice. The study monitors recovery and any complications after the procedure.

What are the possible benefits and risks of participating?
The potential benefit is improved treatment for PE, which may help with breathing and reduce long-term health problems. So far, no complications have occurred in the pilot phase. However, as with any medical procedure, there are risks such as bleeding, injury to blood vessels, or other unexpected issues.

Where is the study run from?
John Paul II Hospital in Krakow, Poland.

When is the study starting and how long is it expected to run for?
March 2023 to December 2026.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Piotr Musiałek, pmusialek@szpitaljp2.krakow.pl
Dr. Łukasz Tekieli, ltekieli@szpitaljp2.krakow.pl

Contact information

Type(s)
Public, Principal Investigator

Contact name
Prof Piotr Musialek

ORCID ID
https://orcid.org/0000-0001-9300-4833

Contact details
Pradnicka 80 str.
Krakow
Poland
31-202
+48 6142111
pmusialek@szpitaljp2.krakow.pl

Type(s)
Scientific

Contact name
Dr Lukasz Tekieli

ORCID ID
https://orcid.org/0000-0002-3431-1013

Contact details
Pradnicka 80 str.
Krakow
Poland
31-202
+48 6142287
ltekieli@szpitaljp2.krakow.pl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Pulmonary thromboembolism mechanical OFFLOAD, right ventricle recovery and clinical outcomes using percutaneous large-bore vs conventional-bore embolectomy in intermediate-high risk Pulmonary Embolism: PE-OFFLOAD (Krakow) Study

Acronym
PE-OFFLOAD (Krakow) Study

Study objectives
There has been a trend to increase the diameter of pulmonary thrombus evacuation catheters; however, no studies to date have directly compared conventional vs. large-bore devices for embolectomy in pulmonary embolism (PE).
This study is performed to evaluate, in patients with intermediate-high risk (submassive) PE undergoing mechanical evacuation of the clots from the lungs, the safety and efficacy of standard-bore vs. large-bore device pulmonary embolectomy catheters. Principal outcomes are clinical recovery and right ventricle recovery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/11/2022, The Bioethical Committee at the Krakow District Medical Chamber (Kurpnicza 11A str., Krakow, 31-123, Poland; +48 126191712; a.krawczyk@hipokrates.org), ref: OIL/KBL/61/2022

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Acute submassive (intermediate-high risk) pulmonary embolism

Interventions
In local anesthesia, after femoral vein puncture and 8F sheath insertion, the 6F pigtail catheter (0.035’ standard wire-supported) is introduced into the pulmonary trunk using a typical technique. The maximal, minimal, and average pulmonary pressures are recorded. Baseline arteriography is performed to localize the thrombus and assess perfusion. With the 0.035’ stiff wire support, the diagnostic catheter is replaced by an 8F or 20F thrombectomy catheter (random treatment allocation occurs via sealed envelopes). Selective cannulation of the affected branches is followed by aspiration of the thrombotic material. Multiple passes are performed as required, depending on the clot burden and location(s). Post-procedural angiography is performed to assess flow restoration and residual thrombus burden. Repeat measurements of pulmonary pressures are taken. If the residual clot burden remains large and there is no significant drop in pulmonary pressure, typical perfusion catheters are introduced to both pulmonary arteries, and infusion of 10mg of rt-PA (each lung) is performed for 2 hours. Finally, the perfusion catheters and the femoral sheath are removed as per standard procedure. Typical non-invasive imaging is performed as per the center routine, involving transthoracic echocardiography and CT angiography at baseline and at 48-hours post-procedure.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Specified

Drug/device/biological/vaccine name(s)
8F Indigo CAT 8 system (Penumbra, Inc.), 20F Magneto Thrombectomy Solutions’ eTrieve Catheter (Magneto Thrombectomy Solutions, Israel)

Primary outcome measure
Combined (hierarchical) clinical endpoint of death by 30-days or NYHA>2 at 7-days post-procedure or oxygen therapy need at 72-hours

Secondary outcome measures
Measured using patient records:
1. Failure to reach at least 30% reduction in RV/LV ratio by CTA at 48 hours
2. Death by 30 days
3. NYHA class greater than 2 at 7 days post-procedure
4. Oxygen therapy needed at 72 hours
5. In-hospital death
6. Major bleeding during procedure
7. Pulmonary artery injury during procedure
8. Cardiac tamponade during procedure

9. Clinical deterioration during the procedure
10. Cardiac arrest during the procedure
11. Duration of hospitalization
12. RV/LV ratio at 48 hours
13. Percentage RV/LV ratio reduction
14. Pulmonary artery systolic pressure reduction at end of procedure
15. Pulmonary artery mean pressure reduction at end of procedure
16. NT-proBNP level at 48 hours (pg/ml)
17. Hemoglobin level at 48 hours (g/dl)
18. Need for red blood cell transfusion
19. Total number of days of hospitalization
20. CTA evidence of pulmonary offload (Miller score) at 48h vs baseline

Overall study start date
30/03/2023

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Clinical signs, symptoms, and presentation consistent with acute pulmonary embolism (PE)
2. PE symptom duration of 14 days or less
3. CT angiography (CTA) evidence of PE
4. RV/LV ratio of 0.9 or greater measured via CT, as determined by the investigational site
5. Heart rate less than 130 beats per minute prior to procedure
6. Subject deemed medically eligible for interventional procedure(s), per institutional guidelines and/or clinical judgment
7. Age between 18 and 74 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
74 Years

Sex
Both

Target number of participants
100

Key exclusion criteria

1. Thrombolytic use within 14 days of baseline CTA
2. Known bleeding diathesis or coagulation disorder
3. Any contraindication to systemic therapeutic doses of heparin or other anticoagulants
4. Hemodynamic collapse at presentation defined as any of the below:
4.1. Need for cardiopulmonary resuscitation
4.2. Systolic blood pressure < 90 mm Hg for at least 15 min
4.3. Drop of systolic blood pressure by at least 40 mm Hg for at least 15 min with signs of end organ hypoperfusion (cold extremities or urinary output < 30 mL/h or mental status changes)
4.4. Need for catecholamine administration to maintain adequate organ perfusion and a systolic blood pressure of > 90 mm Hg
5. Decompensated heart failure
6. Presence of Extra-Corporeal Membrane Oxygenation
7. Major trauma ISS > 15 within 14 days
8. Cardiovascular or pulmonary surgery within last 7 days
9. FiO_2 requirement > 40% or > 6 LPM to keep oxygen saturation > 90%
10. Laboratory findings:
10.1. Hematocrit < 28%
10.2. Platelets < 100,000/μL
10.3. Serum creatinine > 1.8 mg/dL
10.4. INR > 2
11. Left bundle branch block
12. Pulmonary hypertension with peak PAP > 70 mmHg measured either by echocardiography or right heart catheterization
13. Imaging evidence or other evidence that suggests the subject is not appropriate for mechanical thrombectomy intervention
14. Presence of intracardiac lead in right ventricle or atrium
15. Pacemaker or Implantable Cardioverter Defibrillator
16. Presence of intracardiac thrombus
17. Known anaphylactic reaction to radiographic contrast agents that cannot be pre-treated
18. Known right-to-left shunt, for example from large patent foramen ovale or arterial septal defect
19. Known left ventricular ejection fraction ≤ 30%
20. History of severe chronic pulmonary arterial hypertension
21. History of underlying lung disease with oxygen dependence
22. History of chest irradiation
23. History of Heparin Induced Thrombocytopenia (HIT)
24. Female who is pregnant or nursing
25. Current participation in another investigational drug or device treatment study
26. Life expectancy of < 90 days as determined by the investigator
27. Subjects who are intubated

Date of first enrolment
01/04/2023

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Poland

Study participating centre
John Paul II Hospital
Pradnicka 80 str.
Krakow
Poland
31-202

Sponsor information

Organisation
St. John Paul II Hospital

Sponsor details
Pradnicka 80 str.
Krakow
Poland
31-202
+48 6142287
t.durek@szpitaljp2.krakow.pl

Sponsor type
University/education

Website
https://www.uj.edu.pl/pl

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date

31/03/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary

Available on request