PACORUS-D

<u>Pa</u>tient-<u>c</u>entred <u>O</u>utcomes and <u>R</u>esource <u>U</u>tilisation after noncardiac <u>S</u>urgery – <u>D</u>eutschland

FAST FACTS

- There is increased awareness of the importance of functional outcomes for patients
- Information on the epidemiology of patient-centred outcomes after noncardiac surgery in Europe is limited.
- Days Alive and Out of Hospital (DAOH), is an integrative, easily collected and patient-centred outcome after noncardiac surgery; HOWEVER the link between patient-REPORTED disability and Days alive and Out of Hospital is not explored.
- Join PACORUS to answer the questions:

"What is the disability burden of noncardiac surgery? What is the link between Days Alive and Out of Hospital and patient-reported disability after noncardiac surgery?

MEDICAL PROBLEM

While traditionally "surviving the procedure" has been the main benchmark, advances in perioperative safety spotlighted functional outcomes. Accurate assessment of outcomes is crucial across the whole span of perioperative medicine. In daily clinical practice, knowledge on potential outcomes is the foundation for patient information. At population level, knowledge on functional outcomes allows for safety and quality monitoring and it provides guidance for resource allocation. In research, knowledge on perioperative functional outcomes is prerequisite for the development, design, and evaluation of interventions.

Therefore, we aim to investigate "Days alive and out of hospital" and "disability" after noncardiac surgery to contribute to the establishment of those patientcentred outcomes.

OBJECTIVE

1) to quantify patient-reported disability using the 12-item WHODAS after noncardiac surgery at 30 days and 365 days;

2) to assess the link (criterion validity) between DAOH at 30 and 365 days after noncardiac surgery and patientreported disability at 30 days and 365 days.

In patients aged \geq 65 years, a subcohort will assess the impact the frailty and postoperative delirium on 365-day patient-reported disability and on DAOH after noncardiac surgery.

STUDY DESIGN

The focus should be on postoperative functional

procedure: contribute to establishing patient-

outcome rather than "just surviving"

centred outcomes in perioperative medicine!

National prospective, observational, multi–centre cohort study.

Nested cohort study includes PACORUS-CAM. Participation to this nested cohort is optional.

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INCLUSION & EXCLUSION CRITERIA

Inclusion Criteria

Patients aged ≥50 years submitted to non-cardiac, non-neurosurgical, inpatient surgery (thoracic, vascular, abdominal, urinary tract, or orthopaedic/trauma) will be included.

Exclusion Criteria

Patients will be excluded if:

a) they are unwilling or unable to provide informed consent,

b) the procedure is cancelled,

c) they were submitted to >1 surgical procedure in the 7 days prior to enrolment

d) the procedure is performed in analgosedation or local anesthesia

d) they are unable to complete the WHODAS questionnaire (e.g. language or literacy barriers);

e) they were previously enrolled in PACORUS.

OUTCOMES

Main Endpoints:

- "New onset clinically significant

the



disability" at 365 days quantified using the 12-item WHODAS 2.

- Days Alive and Out of Hospital after 30 days

Secondary Endpoints:

- "New onset clinically significant disability" at 30 days and "Clinical relevant disability" at 30 and at 365 days.
- Days Alive and Out of Hospital after 365 days

SAMPLE SIZE AND CENTRES

The planned sample size for Germany is n= 1200. The study is launched by the University Hospitals of Düsseldorf, Aachen, Bonn, Essen, Heidelberg and Köln. Any hospital in Germany providing anesthesia for noncardiac surgery is welcome to participate. <u>Centres are expected to enroll at</u> <u>least 50 patients</u>.

SPONSOR

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STEERING COMMITTEE

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CALL FOR CENTRES

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