Biomarker-Guided Intervention to Prevent Acute Kidney Injury after Major Surgery; The Prospective Multicenter Randomized Controlled Interventional Trial

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The primary objective of this study is to investigate the effect of the implementation of the KDIGO bundle in patients at high risk for AKI after major surgery as compared to standard of care.

Ethical review	Approved WMO
Status	Completed
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON56592

Source
ToetsingOnline

Brief title
BigpAK-2

Condition

- Renal disorders (excl nephropathies)

Synonym
AKI (Acute Kidney Injury); Renal Insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: University Hospital Muenster, Dept. of Anesthesiology, Intensive Care Medicine and Pain Therapy
Source(s) of monetary or material Support: Ministerie van OC&W,bioMerieux

Intervention

Keyword: Acute Kidney Injury, Biomarker, Kidney Diseases, Renal Insufficiency

Outcome measures

Primary outcome

The primary study endpoint is

- occurrence of moderate or severe AKI according to the KDIGO criteria within 3

days after

major surgery (see 16.2)

Secondary outcome

1. Adherence to the implementation of the KDIGO bundle

2. Occurrence and severity of acute kidney injury within 3 days after major

surgery

3. Change in biomarker values during 12 hours after initial measuring of the

[TIMP-2]*[IGFBP7]

4. Free-days of mechanical organ support through to day 3 .

5. Free-days of vasopressors through day 3

6. Need of RRT at day 30 and 90

7. Duration of RRT at day 30 and 90

8. Renal recovery at day 90

9. 30-day and 90-day mortality

10. ICU length-of-stay and Hospital length-of-stay

11. MAKE90 (major adverse kidney events) at day 90

Study description

Background summary

There is no specific therapy for acute kidney injury. It is presumed that supportive measures improve the care and outcome of patients with acute kidney injury. The investigators hypothesize that the implementation of a bundle of supportive measures adapted to patients undergoing major non-cardiac surgery reduces the occurrence of AKI.

This randomized prospective multicenter trial is needed to investigator whether the implementation of the bundle of measures is effective to prevent AKI in high risk patients undergoing major non-cardiac surgery.

Study objective

The primary objective of this study is to investigate the effect of the implementation of the
KDIGO bundle in patients at high risk for AKI after major surgery as compared to standard of
care.

Study design

International, multicenter clinical trial
Two arm, randomized, controlled, parallel-group, trial

Intervention

In the intervention group, the recommendations of the KDIGO group (KDIGO bundle) will be implemented for at least 12 hours, whereas some measures have to be applied for a longer time period. It should be considered for each patient what is best for the patient (individualized approach).
The interventions provided are recommendations and not prescriptions. If it is recommended not use certain medication, less nephrotoxic therapeutic alternatives should be considered.

The bundle includes:
- discontinuation of nephrotoxic drugs if possible for at least 72 hours after randomization
- optimization of fluid status and hemodynamic parameters according to a pre-specified algorithm for the first 12h after randomization

- consideration of a functional hemodynamic monitoring (according to clinical practice in each center, cardiac output can be measured with several devices) for 12 hours after randomization
- close monitoring of serum creatinine, fluid balance and urine output (monitor hourly urine output, serum creatinine and fluid balance every 12 hours) for 72 hours after randomization or until ICU discharge, whatever occurs first
- avoidance of hyperglycemia (>= 150 mg/dl on two consecutive samples more than 3 hours apart) for 72 hours after randomization or until ICU discharge, whatever occurs first
- consideration of alternatives to radio contrast agents for 72 hours after randomization, if possible
- discontinuation of ACEi and ARBs during the first 48h after randomization, if possible
- avoidance of HES, gelatin, and chloride-rich solutions for 72 hours after randomization

Study burden and risks

No side effects are associated with the implementation of the KDIGO bundle.
None of the patients in both groups will be exposed to additional risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients after major surgery who need to be admitted to the ICU
2. Age > 18 years
3. [TIMP-2]*[IGFBP7] >= 0.3 4-18 hours after surgery
4. Inserted jugular central venous line and a urinary catheter
5. Written informed consent
6. At least one additional risk factor for AKI:
a. Age > 75 years
b. Critical illness such as ongoing requirement of vasopressors or mechanical ventilation postoperatively
c. Pre- existing chronic kidney disease (eGFR< 60 ml/ min)
d. Intraoperative use of radio contrast agents.

Exclusion criteria

1. Pregnancy or breastfeeding
2. Pre- existing high stages of chronic kidney disease (>=stage 4 i.e. eGFR < 30 ml/ min)
3. Kidney transplant within the last 12 months
4. Known (Glomerulo-) Nephritis, interstitial nephritis or vasculitis
5. Anuria at inclusion time
6. Preexisting AKI
7. Renal replacement therapy within the last 90 days
8. Indication for renal replacement at the time of inclusion
9. Participation in another interventional trial that investigates a drug/intervention that affects
the kidney function
10. Persons held in an institution by legal or official order
11. Persons with any kind of dependency on the investigator or employed by the responsible
institution or investigator

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	25-03-2024
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	31-01-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT04647396
CCMO	NL81814.018.22