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How well do the kidneys work in critically ill patients in intensive care

Submission date
25/10/2025

Recruitment status
Recruiting

Registration date
15/11/2025

Overall study status
Ongoing

Last Edited
11/11/2025

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims:
The kidneys filter waste products and excess fluids from the body. In certain critically ill patients in the intensive care unit (ICU), the kidneys may function faster than usual - this is known as Augmented Renal Clearance (ARC). As a result, essential medications can be eliminated from the body too quickly, reducing their effectiveness. This study seeks to determine how frequently ARC occurs in ICU patients and to identify related factors, enabling doctors to adjust medication dosages more precisely.

Who can participate?
Adults (aged 18 years or older) admitted to the ICU who are clinically stable and do not have severe kidney disease will be invited to take part in the study.

What does the study involve?
Participants will undergo 24-hour urine collection to assess kidney function. Blood samples will also be taken to measure creatinine levels, which help estimate kidney performance. Additional clinical data, such as age, illness severity, fluid balance, and medications, will be recorded. Taking part will not influence the patient's treatment or care.

What are the possible benefits and risks of participating?
There are no direct benefits for participants, but the results may help improve future medication prescribing for critically ill patients. Risks are minimal and limited to routine sample collection procedures.

Where is the study run from?
The study is being carried out at the National Institute of Traumatology and Orthopaedic Rehabilitation (NITOR) in Dhaka, Bangladesh.

When is the study starting and how long is it expected to run for?
The study is scheduled to begin in December 2025 and will run for about 12 months.

Who is funding the study?
The Directorate General Medical Education (DGME) is funding this study through the 2025–26 Research Grant Program.

Who is the main contact?
Dr Syed Tariq Reza, drtariq@nitor.gov.bd

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
59.14.0000.138.001.16.0002.24.72

Study information

Scientific Title
Augmented renal clearance in patients admitted to the intensive care unit: a prospective observational study

Acronym
ARC-ICU

Study objectives
This prospective observational study investigates the prevalence of augmented renal clearance (ARC) in adult patients admitted to the intensive care unit (ICU) for more than 24 hours. ARC is defined as a 24-hour measured creatinine clearance (CrCl) ≥120 mL/min/1.73 m². The study also aims to identify demographic, physiological, and clinical risk factors associated with ARC, compare measured and estimated CrCl values, and evaluate the impact of ARC on clinical outcomes, including ICU length of stay, mortality, and treatment response.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/10/2024, Institutional Ethical Review Board (IERB) (Shaheed Suhrawardy Medical College, Sher E Bangla Nagar, Dhaka, 1207, Bangladesh; +880 (0)29130295; principal_shsmc@yahoo.com), ref: 59.14.0000.138.001.16.0002.24.72

Study design
Prospective observational study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Augmented renal clearance (ARC) in critically ill patients

Interventions
Eligible adult ICU patients (≥18 years) will undergo serial 24-hour urine collections on days 1, 3, 5, and 7 of ICU admission. In non-catheterized patients: Urine collection begins after the bladder is emptied, followed by a complete 24-hour collection in a refrigerated or ice-cooled container. In catheterized patients: The urine bag is emptied at the start of collection and every 2 hours thereafter into a refrigerated or ice-cooled container. Urinary creatinine concentrations will be measured enzymatically. Serum creatinine will be measured 12 hours after the start of urine collection. CrCl24h will be calculated and normalized to a body surface area (BSA) of 1.73 m². Demographic and clinical data (age, sex, BSA, admission diagnosis, vital signs, APACHE II, SOFA scores, fluid balance, vasopressor and antibiotic use, comorbidities) and laboratory results (serum creatinine, urine creatinine, measured and estimated CrCl) will be recorded. ARC is defined as CrCl >130 mL/min/1.73 m². Patients will be followed for 28 days or until discharge /death for outcome analysis (ICU length of stay, mortality, treatment response).

Intervention Type
Other

Primary outcome(s)
Prevalence of ARC (≥120 mL/min/1.73 m²) as measured by 24-hour urinary creatinine clearance within first 7 days of ICU admission

Key secondary outcome(s))
1. Risk factors associated with ARC (demographic, physiological, and clinical parameters) within the first 7 days of ICU admission
2. Comparison between measured and estimated CrCl (using Cockcroft–Gault formula) within the first 7 days of ICU admission
3. Clinical outcomes (ICU length of stay, mortality, treatment response) up to 28 days or until ICU discharge/death

Completion date
15/10/2026

Eligibility

Key inclusion criteria
1. Adults aged ≥18 years
2. ICU stay ≥24 hours
3. Informed consent obtained from patient or legal representative

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Chronic kidney disease (CKD stage ≥3 or baseline eGFR <60 mL/min)
2. Receiving renal replacement therapy
3. Kidney transplant recipients

4. Pregnant or lactating women
5. Incomplete urine collection or missing laboratory data
6. Hemodynamic instability precluding safe sampling

Date of first enrolment
01/11/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Bangladesh

Study participating centre
National Institute of Trauma & Orthopaedic Rehabilitation (NITOR)
Intensive care Unit (ICU), National Institute of Trauma & Orthopaedic Rehabilitation (NITOR)
Sher E Bangla Nagar
Dhaka
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Study participating centre
Shaheed Suhrawardy Medical College Hospital
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Sponsor information

Organisation
National Institute of Traumatology & Orthopaedic Rehabilitation

ROR
https://ror.org/01xg2j237

Funder(s)

Funder type
Government

Funder Name
Directorate General of Medical Education (DGME)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request to the principal investigator Dr Syed Tariq Reza (rezatariq7@gmail.com)
Type of data shared: De-identified clinical and laboratory data concerning renal clearance measurements and patient characteristics.
Dates of availability: The data will be accessible upon reasonable request following publication of the main findings (anticipated in 2027).
Consent for data sharing: Consent for anonymized data use will be obtained from each participant or their legal guardian.
Data anonymization: All personal identifiers will be removed before data sharing.
Ethical/legal restrictions: Data sharing will adhere to institutional ethics approvals and national data protection regulations.
Additional comments: The study team will review data requests and approve them based on research relevance and ethical compliance.

IPD sharing plan summary
Available on request