ISRCTN13470139 https://doi.org/10.1186/ISRCTN13470139

The effect of starting dialysis earlier than usual in patients with damaged kidneys

Submission date
03/02/2019

Recruitment status
No longer recruiting

Registration date
18/02/2019

Overall study status
Completed

Last Edited
07/08/2023

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
More than 1 in 2 critically ill patients in the intensive care unit (ICU) develop acute kidney injury (AKI). A proportion of patients need dialysis treatment, also known as replacement therapy (RRT). The aim of RRT is to remove toxins and excess fluid which may have accumulated because of kidney failure. At present it is not clear whether it is best to start RRT only when patients have evidence of severe AKI or whether it is better to initiate RRT earlier, i.e. as soon as patients have signs of impaired kidney function.

Who can participate?
Patients aged over 18 years admitted to the intensive care unit with serious kidney problems.

What does the study involve?
RRT consists of having a catheter (a tube or 'line') in a vein in the neck or in the groin through which blood flows to a dialysis machine where it is cleansed and excess water is removed. The cleansed blood is then returned to the patient via the catheter.

What are the possible benefits and risks of participating?
RRT can be lifesaving but has side effects, possibly including bleeding and bloodstream infections. Importantly, if at any stage the treating clinician feels that RRT is mandatory or alternatively should not be started, their judgement will override. Also, there will be no change in any clinical management and no extra blood samples will be taken.

Where is the study run from?
Guy's & St Thomas Hospital, Westminster Bridge Road, London, SE1 9RT, UK.

When is the study starting and how long is it expected to run for?
February 2018 to March 2020.

Who is funding the study?
The National Institute for Health Research (United Kingdom) Health Technology Assessment programme.

Who is the main contact?
Mrs. Marlies Ostermann, Marlies.Ostermann@gstt.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Marlies Ostermann

Contact details
Guy's & St Thomas Hospital
Department of Critical Care
Westminster Bridge Road
London
United Kingdom
SE1 9RT
+44 (0)2071883038
Marlies.Ostermann@gstt.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
191390

ClinicalTrials.gov number
NCT02568722

Secondary identifying numbers
IRAS 191390

Study information

Scientific Title
STandard versus Accelerated initiation of Renal Replacement Therapy in Acute Kidney Injury (STARRT-AKI): a multi-centre, randomized, controlled trial

Acronym
STARRT-AKI

Study objectives
In critically ill patients with severe acute kidney injury (AKI), randomization to accelerated initiation of renal replacement therapy (RRT), compared to a conservative strategy consistent

with standard care, leads to:
1. improved survival at 90 days; and
2. better recovery of kidney function, defined as independence from dialysis at 90 days.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/05/2017, Camberwell St Giles REC (Institute of Psychiatry, Seminar Room 6, IOP Main Building, SE5 8AF, +44 (0) 207 1048044, NRESCommittee.London-CamberwellStGiles@nhs.net), ref:

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute kidney injury

Interventions
Patients in the ICU with early AKI will be randomised to RRT using standard criteria versus accelerated (earlier) RRT. Patients randomised to the accelerated arm will be started on RRT within 12 hours of eligibility. In patients randomised to standard initiation, RRT will be discouraged until serum potassium >5.9 mmol/L, pH <7.21 or serum bicarbonate <13 mmol/L, respiratory failure due to fluid overload, or persistent AKI stage 2 or 3 for >72 hours.

Intervention Type
Procedure/Surgery

Primary outcome measure
Mortality measured at 90 days

Secondary outcome measures
Recovery of kidney function defined as independence from dialysis at 90 days

Overall study start date
01/02/2018

Completion date
31/05/2021

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Admission to an intensive care unit (ICU)
3. Evidence of kidney dysfunction [serum creatinine ≥100 µmol/L in women and ≥ 130 µmol/L in men]
4. Evidence of severe AKI

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
580

Total final enrolment
2927

Key exclusion criteria
1. Lack of commitment to provide RRT as part of limitation of ongoing life support.
2. Presence of a drug overdose that necessitates initiation of RRT.
3. Any RRT within the previous 2 months.
4. Kidney transplant within the past 365 days.
5. Known pre-hospitalization advanced chronic kidney disease, defined by an estimated glomerular filtration rate <20 mL/min/1.73 m2 in a patient who is not on chronic dialysis.
6. Presence or clinical suspicion of renal obstruction, rapidly progressive glomerulonephritis, vasculitis, thrombotic microangiopathy (eg, thrombotic thrombocytopenic purpura, hemolytic uremic syndrome, malignant hypertension, scleroderma renal crisis) or acute interstitial nephritis.
7. Likelihood that an absolute indication for RRT will arise in the subsequent 24 hours based on the most recent blood work for the following parameters: serum K >5.5
8. Likelihood that an absolute indication for RRT will arise in the subsequent 24 hours based on the most recent blood work for the following parameters: serum bicarbonate <15 mmol/L

Date of first enrolment
01/02/2018

Date of final enrolment

31/05/2020

Locations

Countries of recruitment
Canada

England

United Kingdom

Study participating centre
Guy's & St Thomas Hospital
Westminster Bridge Road
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
University of Toronto

Sponsor details
Applied Health Research Centre
30 Bond Street
Toronto
Canada
M5B 1W8

Sponsor type
Research organisation

ROR
https://ror.org/03dbr7087

Funder(s)

Funder type
Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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

Intention to publish date
31/05/2022

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/07/2020	18/11/2022	Yes	No
Protocol file	version 3.3	15/12/2020	07/08/2023	No	No