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Can increased urine flow encouraged by the drug furosemide and increased water intake prevent kidney injury caused by the contrast media used in angiography procedures in patients with reduced kidney function?

Submission date
01/07/2019

Recruitment status
No longer recruiting

Registration date
23/07/2019

Overall study status
Completed

Last Edited
23/10/2020

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Coronary artery disease (CAD) is common throughout the world and is when the coronary arteries (the blood vessels supplying the heart with oxygen) become blocked or damaged. This can lead to angina (heart pain) and myocardial infarction (heart attack). CAD is caused by the narrowing or blockage of the coronary arteries by fatty deposits and blood clots. CAD can be treated by changing the patient's lifestyle and diet, drugs that open up coronary arteries, or procedures to physically open the arteries. Examples of procedures used are balloon dilatation or stent implantation, where a balloon or wire-mesh tube (stent) attached to a wire is inserted into an artery in the leg or arm and guided into the coronary artery. The balloon can be inflated inside the artery to open it and the stent can be left inside to hold the artery open. The patient can be awake with local pain relief for these procedures. X-rays are used throughout the procedure to see where the blockages are and where the ballooon or stent are. This requires injection of a liquid called contrast medium into the blood to make the blood vessels visible in the X-ray, which is known as angiography. Contrast media are generally safe, but they can cause problems such as acute kidney injury (damage to the kidney), particularly in patients with kidney disease or those who undergo complex procedures requiring multiple treatment sessions or those who need larger amounts of contrast agents. There are different methods used by doctors to decrease the chance acute kidney injury, which have different success rates. Most of these preventive measures involve giving the patient water (hydration) either through the mouth or through a vein. This study will investigate whether matched hydration (giving the patient the same amount of water as they have passed in their urine) alone or combined matched hydration and furosemide is more effective at preventing acute kidney injury. Furosemide is a diuretic drug, which means it increases the production of urine, so matched hydration in the patients receiving furosemide would be expected to involve more water intake.

Who can participate?
Patients with kidney problems who are having a procedure to treat CAD involving contrast media injection.

What does the study involve?
The participants will all have the CAD procedure as normal. They will be randomly allocated to receive matched hydration alone or matched hydration and furosemide. The hydration will start before the injection of contrast media and will continue throughout the procedure and for 4 hours afterwards.

What are the possible benefits and risks of participating?
There might be a reduced risk of CIN. Both groups will be closely monitored for signs of CIN and will be managed with standard treatments if CIN occurs.

Where is the study run from?
University of Sulaimani College of Medicine (Iraq)

When is the study starting and how long is it expected to run for?
November 2017 to December 2019

Who is funding the study?
The researcher is funding the study.

Who is the main contact?
Dr Aram Mirza, aram@arammirza.com

Contact information

Type(s)
Public

Contact name
Dr Aram Mirza

ORCID ID
https://orcid.org/0000-0002-4842-2195

Contact details
Sulaimaniyah
Sulaimaniyah
Iraq
46001
009647701570490
aram@arammirza.com

Type(s)
Scientific

Contact name
Dr Aram Mirza

ORCID ID
https://orcid.org/0000-0002-4842-2195

Contact details
Sulaimaniyah
Sulaimaniyah
Iraq
46001
009647701570490
aram@arammirza.com

Additional identifiers

Protocol serial number
-

Study information

Scientific Title
Contrast-Induced Nephropathy: Evaluation of MAtched hydration and furosemide in risky patients undergoing chronic total occlusion-percutaneous coronary intervention (CINEMA)

Acronym
CINEMA

Study objectives
Contrast-induced nephropathy (CIN) is the third most common cause for in hospital acute kidney injury. Acute and 1- and 5-year mortality and morbidity (e.g. stroke, myocardial infarction and vessel re-occlusion) incidences are higher in patients who develop CIN as opposed to patients without CIN.
Despite the increasing use of pre- and post-procedure hydration protocols and low osmolar instead of high osmolar iodine-containing contrast media, the incidence of CIN is still significant (2-13%), demanding an active role in this area to find a better approach. Our hypothesis is that matched hydration and furosemide is an effective method for prevention of CIN.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/01/2018, University of Sulaimani College of Medicine Ethical Committee (c/o Assistant Professor Bakhtiar Mohamed Mahmoud, Department of Medicine, University of Sulaimania School of Medicine, Sulaimania, Kurdistan, Iraq; 009647501540146; bakhtiar.mahmoad@univsul.edu.iq), ref: 60

Primary study design
Interventional

Study design
Single-center randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of contrast-induced nephropathy in patients with impaired renal function undergoing percutaneous coronary interventions for chronic total occlusion of the coronary arteries

Interventions
After patients have agreed to take part in the study, those with baseline eGFR <60 ml/min/1.73 m2 will be randomly assigned to either control or treatment group. All patients will have a Foley catheter inserted.
The treatment group will have a fluid bolus of 250 ml of normal saline (reduced to 150 ml in those with left ventricular [LV] dysfunction) over 30 min and a start dose of furosemide will be administered (0.25-0.5 mg/kg). Injection of contrast medium will be delayed until urine flow rate of >300 ml/h is obtained. The hydration will be continued throughout the duration of the procedure and will last 4 h following the procedure. Urine flow rate is maintained at >300 ml/h with additional doses of furosemide if necessary.
The control group will be offered prehydration with sodium chloride 0.9% at 1-1.5 mL/kg/h for 12 h pre-procedure and up to 12 h post-procedure

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Furosemide

Primary outcome(s)
Contrast-induced acute kidney injury defined as an increase in serum creatinine concentration of 25% or 0.5 mg/dl from the baseline to 48 h after contrast medium exposure

Key secondary outcome(s)
N/A

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Estimated GFR of <60 mL/min/1.73 m2
2. Receiving contrast media for invasive coronary angiography or intervention

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
All

Key exclusion criteria
1. Aged under 18 years
2. Allergy to furosemide
3. Severe LV dysfunction
4. Receiving dialysis

Date of first enrolment
01/01/2018

Date of final enrolment
01/06/2019

Locations

Countries of recruitment
Iraq

Study participating centre
Slemani Cardiac Hospital
Sulaimaniyah
Kurdistan Region
Sulaimaniyah
Iraq
46001

Sponsor information

Organisation
University of Sulaimani College of Medicine

ROR
https://ror.org/00saanr69

Funder(s)

Funder type
Other

Funder Name
Investigator-funded

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Available on request