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A randomized clinical trial comparing nitrofurazone-coated and uncoated urinary catheters in kidney transplant recipients

Submission date
22/05/2018

Recruitment status
No longer recruiting

Registration date
30/05/2018

Overall study status
Completed

Last Edited
12/12/2018

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Urinary tract infections are frequent complications early after kidney transplantation, and although simple infection control measures may be effective, the use of antimicrobial coated catheters in settings other than transplantation has shown promising results for infection prevention. The aim of this study is to compare the effectiveness of nitrofurazone-coated silicone urinary catheters with non-impregnated silicone urinary catheters at reducing bacteriuria (bacteria in urine) and urinary tract infections in kidney transplant recipients.

Who can participate?
Living donor kidney transplant recipients

What does the study involve?
Participants are randomly allocated to either a nitrofurazone-coated silicone urinary catheter or a non-impregnated silicone urinary catheter. The total duration of treatment was 7 days. Rates of bacteriuria, urinary infection and antimicrobial resistance are measured at the start of the study, and at 7, 14 and 30 days after kidney transplantation.

What are the possible benefits and risks of participating?
The possible benefits are the reduction of bacteriuria and urinary infection after kidney transplantation. The risks to the participants would be discomfort with the use of the bladder catheter, hematuria (blood in urine), and obstruction of the urinary flow.

Where is the study run from?
Hospital do Rim, São Paulo (Brazil)

When is the study starting and how long is it expected to run for?
June 2010 to December 2014

Who is funding the study?
CAPES Scholarship (Brazil)

Who is the main contact?
Dr Fernando Menezes

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0734/10

Study information

Scientific Title
A randomized clinical trial comparing nitrofurazone-coated and uncoated urinary catheters in kidney transplant recipients

Study objectives
Urinary tract infections (UTI) are the most common bacterial infections in kidney transplant recipients, accounting for significant morbidity and increased costs. The incidence of UTI in kidney transplant recipients ranges from 7% to 43% and occur mainly during the first month after transplantation. Urinary tract infections and asymptomatic bacteriuria have been associated with impaired graft function, frequent, and sometimes unnecessary, antibiotic use and may precede pyelonephritis, with relevant clinical consequences. Thus, prevention of urinary tract infections and asymptomatic bacteriuria, mainly employing standard nosocomial infection prevention measures may have a significant impact after kidney transplantation.

The purpose of this study was to compare the efficacy of Nitrofurazone-coated silicone urinary catheters with non-impregnated silicone urinary catheters in reducing bacteriuria and urinary tract infections in kidney transplant recipients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics and Research Committee of the Universidade Federal de São Paulo, 08/12/2010, ref: 0734 /10

Study design
Pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Urinary tract infections

Interventions
Participants were randomized one day before kidney transplantation with a computer-generated system in a 1:1 ratio to a 3-way nitrofural-impregnated silicone catheter (StrataNF, Rochester Medical, Stewartville, Minnesota, USA) or a 3-way non-impregnated silicone catheter (Silmag, Silmag Brasil Produtos Médicos, Sorocaba, São Paulo, Brazil). The principal investigator, clinicians, nurses and participants were not masked to the allocated intervention because of the distinctive appearances of each catheter.

All patients were maintained on a triple immunosuppressive regimen (usually tacrolimus, mycophenolic acid and prednisone), with or without induction (antithymocyte globulin). Acute rejection treatment consisted of intravenous corticosteroids bolus for three to five consecutive days, followed by a course of antithymocyte globulin in the case of corticoid resistance. Perioperative Cefazolin was used as surgical prophylaxis for 24 hours after transplantation, and trimethoprim/sulfamethoxazole (80 mg / 400 mg) was maintained daily for six months.

The total duration of treatment was 7 days. The follow-up was 1 year after kidney transplantation.

Intervention Type
Device

Primary outcome measure
Asymptomatic bacteriuria rates, urinary infection rates and antimicrobial resistance rates at baseline (transplant day), 7 days, 14 days and 30 days after kidney transplantation

Secondary outcome measures
Incidence of discomfort, etiological agents and urinary sediment at baseline (transplant day), 7 days, 14 days and 30 days after kidney transplantation.

Overall study start date
01/06/2010

Completion date
31/12/2014

Eligibility

Key inclusion criteria
Patients included were older than 18 years and consecutively undergoing urethral catheterization for kidney transplantation with a living donor from March 2013 to December 2014

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
214 patients

Key exclusion criteria
1. Patients with asymptomatic bacteriuria or urinary tract infection at baseline
2. Deceased kidney transplant donors
3. Patients with known hypersensitivity to nitrofurantoin
4. Pregnancy
5. Those refusing to sign the informed consent form

Date of first enrolment
04/03/2013

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Brazil

Study participating centre
Hospital do Rim
960, Borges Lagoa Street
São Paulo
Brazil
04038-002

Sponsor information

Organisation
Hospital do Rim

Sponsor details
960 Borges Lagoa Street
São Paulo
Brazil
04038002

Sponsor type
Hospital/treatment centre

Website
www.hrim.com.br

ROR
https://ror.org/045e9rc94

Funder(s)

Funder type
Government

Funder Name
CAPES Scholarship (Brazil)

Results and Publications

Publication and dissemination plan
The additional documents will be available. The protocol is not available online. Planned submission of the results to the American Journal of Infection Control in June 2018.

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan
The dataset will be held at the university (Universidade Federal de São Paulo).

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2019		Yes	No