ISRCTN23941498 https://doi.org/10.1186/ISRCTN23941498

Outcome of kidney transplantation with Bricker-type ureterointestinal anastomosis in patients with lower urinary tract dysfunction.

Submission date
01/11/2014

Recruitment status
No longer recruiting

Registration date
26/01/2015

Overall study status
Completed

Last Edited
15/10/2020

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
Kidney transplantation is the best treatment for kidney failure but for patients with lower urinary tract (bladder and urethra) dysfunction (for example, due to an infection), it is often impossible perform that surgery in a classic way. A Bricker-type ureterointestinal anastomosis (a tube connecting the ureter to the small intestine) is a widely used technique for performing ureteroenteric anastomosis (a technique for diverting the flow of urine from its normal route) in these cases. Here, we want to investigate how well patients do having undergone a Bricker-type ureterointestinal anastomosis during their kidney transplant compared to patients who have a classic kidney transplant

Who can participate?
Adults (aged 20-64) with lower urinary tract dysfunction that underwent a kidney transplantation with Bricker-type ureterointestinal anastomosis from 1999 to 2014 (experimental group). A control group consisting of participants who have had a classic kidney transplant, receiving either the second kidney of a deceased donor from which a participant from the experimental group has been given the first, or a kidney from a living donor is also recruited. In the case of patients whose kidney is from living donor, comparisons are made with people in the experimental group who have also received a kidney from a living donor.

What does the study involve?
Participants are invited to our hospital, where they undergo an examination and a number of tests (blood tests, urine tests, ultrasound, renal scintigraphy). The results from the experimental group are then compared to those of the control group.

What are the possible benefits and risks of participating?
All participants will be given the results of our tests. If we find some disorders or abnormalities we will try to treat them. The risk to participants is close to zero.

Where is the study run from?
Department of General and Transplantation Surgery of Infant Jesus Hospital in Warsaw (Poland)

When is the study starting and how long is it expected to run for?
November 2014 to September 2015.

Who is funding the study?
Medical University of Warsaw (Poland)

Who is the main contact?
Agnieszka Jóźwik
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Contact information

Type(s)
Scientific

Contact name
Miss Agnieszka Jóźwik

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Outcome of kidney transplantation with Bricker-type ureterointestinal anastomosis in patients with lower urinary tract infection: a observational single-centre trial

Acronym
N/A

Study objectives
Study hypothesis is that outcome of kidney transplantation with Bricker-type ureterointestinal anastomosis, is as good as outcome of kidney transplantation with normal urinary drainage. There is the same kidney function, number of complications after transplantation, graft and patient survival.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethical Committee of Medical University of Warsaw, 04/11/2014, ref. KB/215/2014

Study design
Observational single-centre trial

Primary study design
Observational

Secondary study design
Single-centre

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Patients with end stage renal disease and lower urinary tract dysfunction who underwent kidney transplantation with Bricker-type ureterointestinal anastomosis in our center.

Interventions
We will compare results of the following for experimental and control group patients:
1. Blood tests
2. Urine tests
3. Ultrasound
4. Renal scintigraphy
5. eGFR (creatinine clearace, Cocroft-Gault formula, MDRD formula, CKD - EPI formula)

Intervention Type
Other

Primary outcome measure
1. Blood tests: complete blood count, sodium, potassium, chloride, bicarbonate, blood urea nitrogen, magnesium, creatinine, glucose, calcium, lipid profile, cystatin C, C Reactive Protein, AST, ALT, bilirubin, serum albumin, vitamin B12, folic acid, transferrin, ferritin, parathormone.
2. Urine tests: routine and microscopy, cretinine, bacterial cultures.
3. Ultrasound of the abdomen and graft.
4. Renal scintigraphy.

Secondary outcome measures
N/A

Overall study start date
12/11/2014

Completion date
30/09/2015

Eligibility

Key inclusion criteria
1. Patients with lower urinary tract dysfunction who underwent kidney transplantation with Bricker-type ureterointestinal anastomosis at study center, from 1999 to 2014 (experimental group)
2. Age range 20 to 64
3. Control group - patients who had kidney transplantation and obtained a kidney from the same deceased donor as a participant from the experimental group.
4. In the case of patients, who have received a kidney from a living donor, comparisons between control and experimental group participants will be made with others that have recieved a kidney from a living donor.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
74 (37 patients that have undergone kidney transplantation with Bricker-type ureterointestinal anastomosis and 37 patients that have undergone kidney transplantation with normal urinary drainage).

Key exclusion criteria
Patients who refuse their participation in this study.

Date of first enrolment
12/11/2014

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
Poland

Study participating centre

Nowogrodzka 59
Warsaw
Poland
02-006

Sponsor information

Organisation
Medical University of Warsaw (Poland)

Sponsor details
Żwirki i Wigury 61
Warsaw
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Sponsor type
University/education

ROR
https://ror.org/04p2y4s44

Funder(s)

Funder type
University/education

Funder Name
Medical University of Warsaw (Poland)

Alternative Name(s)
Medical University of Warsaw

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Poland

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration