ISRCTN28160715 https://doi.org/10.1186/ISRCTN28160715

A retrospective review of the outcomes of patients receiving a bovine artery graft for dialysis access

Submission date
10/05/2021

Recruitment status
No longer recruiting

Registration date
16/06/2021

Overall study status
Completed

Last Edited
16/06/2021

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Normally, the kidneys filter the blood, removing harmful waste products and excess fluid and turning these into urine to be passed out of the body. Dialysis is a procedure to remove waste products and excess fluid from the blood when the kidneys stop working properly. Dialysis often involves diverting blood out of the body to a machine that acts similarly to a kidney to filter the blood and then is returned to the body. In order to remove and return the blood from the body on multiple occasions for dialysis, a point of access will be created surgically. There are a number of methods that may be used including an arteriovenous graft which is a looped tube that connects an artery to a vein. This tube may be made of plastic such as polytetrafluoroethylene (PTFE) or biological material such as bovine carotid artery.

This study will compare whether the grafted tube remains open to the flow of blood 12 months after surgery in patients who received a bovine carotid artery graft.

Who can participate?
Adult patients who received surgical placement of a bovine carotid artery graft between 2017-2018

What does the study involve?
This study involves a retrospective review of all patients undergoing surgical placement of a bovine carotid artery graft for dialysis access between 2017-2018 at Louisiana State University Health Sciences Center.

Data on the extent to which the graft remains open to allow blood flow (patency) will be collected from patient records for the whole cohort and results determined based on gender, BMI, and indication for use. The outcomes of bovine carotid artery grafts will be compared to polytetrafluoroethylene (PTFE) grafts performed at the same institution between 2013 and 2016.

What are the possible benefits and risks of participating?
There is no human risk involved as this is retrospective study.

Where is the study run from?
Louisiana State University Health Sciences Center (USA)

When is the study starting and how long is it expected to run for?
From September 2019 to September 2021

Who is funding the study?

Who is the main contact?
Dr Chiranjiv Virk, cvirk@lsuhsc.edu

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
STUDY00001258

Study information

Scientific Title
A retrospective review of bovine artery graft patency: a single site study

Study objectives
To look at the outcome of the bovine carotid artery grafts for dialysis at a single institution, and compare these results for polytetrafluoroethylene (PTFE) grafts

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/10/2019, Louisiana State University Health Sciences Center - Shreveport Institutional Review Board (LSUHSC-S IRB) (2nd Floor, Admin Building, 1501 Kings Hwy, Shreveport, LA 71103; +1 318-813-1359; no email address available), ref: STUDY00001258

Study design
Retrospective review

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bovine artery graft, arteriovenous graft, end-stage renal disease, hemodialysis, dialysis access

Interventions
The retrospective review will involve the review of participant charts between 01/01/2017 and 15/08/2019 to assess patency following bovine artery graft procedure.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Primary and primary-assisted patency rates at 12 months measured from patient charts at a single timepoint

Key secondary outcome(s))
Secondary patency at 12 months measured from patient charts at a single timepoint

Completion date
10/09/2021

Eligibility

Key inclusion criteria
Bovine artery graft placed between 01/01/2017 and 15/08/2019

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
74

Key exclusion criteria
1. Unable to consent
2. Aged <18 years
3. Pregnancy
4. Prisoners

Date of first enrolment
01/01/2017

Date of final enrolment
15/08/2019

Locations

Countries of recruitment
United States of America

Study participating centre
Louisiana State University Health Sciences Center
1501 K Hway
Shreveport
United States of America
71130

Sponsor information

Organisation
Louisiana State University Health Sciences Center New Orleans

ROR
https://ror.org/01qv8fp92

Funder(s)

Funder type
Other

Funder Name

Not 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

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes