Manchester vascular access study

Submission date	Recruitment status	Prospectively registered
03/04/2014	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
03/04/2014	Completed	Results
Last Edited	Condition category	Individual participant data
24/09/2020	Urological and Genital Diseases	Record updated in last year

Plain English summary of protocol

Background and study aims

Haemodialysis (HD) is a life-saving and life-sustaining treatment. Effective HD requires a reliable, long-term and safe vascular access (approach into the blood stream). Native AV fistulae (AVFs) are the preferred vascular access for their low complication rates and longevity. However, AVFs have high early failure rates, but once matured they have a relatively longer operational life and a lower complication rate, especially from infections, when compared to prosthetic grafts (AVGs) and dialysis catheters. This study aims to understand the natural history of AVF maturation and identify factors influencing outcomes.

Who can participate?

Patients in need of upper limb AVF for haemodialysis

What does the study involve?

The patient attends three extra scans. Blood samples are taken and the patient is followed up over a monthly basis for a year. They may have two additional visits to the hospital.

What are the possible benefits and risks of participating?

Participants receive two additional scans and are closely monitored. Participants may need to have extra needles inserted for research blood tests, although every effort will be made to take them at the scheduled blood tests, thus further reducing the small risks associated with taking blood from the veins.

Where is the study run from?

Central Manchester University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for? October 2011 to March 2022

Who is funding the study? Bioconnect Systems Inc. (USA)

Who is the main contact? Miss Carla Barrett carla.barrett@cmft.nhs.uk

Contact information

Type(s)

Scientific

Contact name

Miss Carla Barrett

Contact details

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Additional identifiers

Protocol serial number

12048

Study information

Scientific Title

Understanding haemodialysis vascular access maturation: a prospective observational study to understand the natural history and biology of AV access maturation and identify risk factors for AVF failure

Acronym

MANVAS

Study objectives

To understand the natural history of AVF maturation and identify factors influencing outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee North West Preston, 17/02/2011, ref. 11/H1016/3

Study design

Randomised; Interventional; Design type: Not specified, Screening

Primary study design

Interventional

Study type(s)

Screening

Health condition(s) or problem(s) studied

Topic: Renal disorders; Subtopic: Renal disorders; Disease: All Renal disorders

Interventions

Extra bloods at baseline: Patients will have an extra blood test at this point for haematological /biochemical parameters and DNA/stem cell sampling and analysis. Extra blood tests will be optional and will not be mandatory for all participating centres. Perioperatively - blood tests, patients will undergo further blood tests peri-operatively and these will be linked to their perioperative clinically indicated blood tests; blood tests will be optional and are not mandatory for study inclusion. US scan - follow-up, Doppler ultrasound scan will be used to assess maturation.

It is anticipated that most patients will have two extra visits with tests during their visits (routine postoperative visit and scan at 6 weeks is standard clinical practice). For the minority of patients who have not used their fistula by 6 months, we will perform the final study evaluation with US at 6 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Successful (unassisted) maturation defined as either A or B A: Use of the AVF with two needles

Key secondary outcome(s))

Not provided at time of registration

Completion date

01/03/2022

Eligibility

Key inclusion criteria

- 1. The participant is in need of AV dialysis access for haemodialysis.
- 2. Participant is available and can return for follow-up visits

Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Inability to give consent and comply with the study follow-up schedule

Date of first enrolment

20/10/2011

Date of final enrolment

30/06/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Manchester Royal Infirmary

Manchester United Kingdom M13 9WL

Sponsor information

Organisation

Central Manchester & Manchester Childrens University Hospital NHS Trust (UK)

ROR

https://ror.org/00he80998

Funder(s)

Funder type

Industry

Funder Name

Bioconnect Systems Inc. (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No Yes