

# Manchester vascular access study

<b>Submission date</b> 03/04/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/04/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 24/09/2020	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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](mailto:carla.barrett@cmft.nhs.uk)

# Contact information

## Type(s)

Scientific

## Contact name

Miss Carla Barrett

## Contact details

Manchester Royal Infirmary

Oxford Road

Manchester

United Kingdom

M13 9WL

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Carla.Barrett@cmft.nhs.uk

# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Screening

**Participant information sheet**

Not available in web format, please contact [carla.barrett@cmft.nhs.uk](mailto:carla.barrett@cmft.nhs.uk) to request a patient information sheet

**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 peri-operative 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 measure**

Successful (unassisted) maturation defined as either A or B

A: Use of the AVF with two needles

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

20/10/2011

**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

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

Planned Sample Size: 250; UK Sample Size: 250

## 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

England

United Kingdom

## Study participating centre

**Manchester Royal Infirmary**

Manchester

United Kingdom

M13 9WL

# Sponsor information

**Organisation**

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

**Sponsor details**

Department of Gastroenterology  
Manchester Royal Infirmary  
Oxford Road  
Manchester  
England  
United Kingdom  
M13 9PL

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/00he80998>

**Funder(s)****Funder type**

Industry

**Funder Name**

Bioconnect Systems Inc. (USA)

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

2014 thesis in [https://www.research.manchester.ac.uk/portal/files/54552626/FULL\\_TEXT.PDF](https://www.research.manchester.ac.uk/portal/files/54552626/FULL_TEXT.PDF)  
(added 01/09/2020)

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration