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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
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Contact information

Type(s)
Scientific

Contact name
Miss Carla Barrett

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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 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
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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 (added 01/09/2020)

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration