ISRCTN77018822 https://doi.org/10.1186/ISRCTN77018822

Best Extremity Survival Times And Concurrent Complications: Examination of Secondary access Study (BEST ACCESS) Pilot Study

Submission date
31/07/2008

Recruitment status
No longer recruiting

Registration date
17/10/2008

Overall study status
Completed

Last Edited
01/07/2010

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
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Charmaine Lok

Contact details
Toronto General Hospital
200 Elizabeth Street
8NU-Room 844
Toronto
Canada
M5G 2C4
+1 416 340 4140
charmaine.lok@uhn.on.ca

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Best Extremity Survival Times And Concurrent Complications: an Examination of Secondary access Study - pilot trial

Acronym
BEST ACCESS Pilot Study

Study objectives
Chronic kidney disease has become an epidemic with rapidly increasing numbers of people worldwide reaching end stage renal disease when survival becomes dependent on renal replacement therapy. In North America, there are over 450,000 people requiring dialysis, 80 - 90% of whom undergo haemodialysis (HD). Once on HD, a reliable conduit between the patient's blood circulation and the dialysis machine is required via a vascular access (VA). The vascular accesses have limited longevity, and patients often require multiple accesses during their lifetime on dialysis, averaging 2.77 accesses per patient.

Currently, all national HD guidelines recommend the initial creation of an arteriovenous fistula (AVF), at the most distal site possible, (e.g. radiocephalic or forearm site) in order to preserve more proximal sites for later VA creation when the original forearm access eventually fails. However, the optimal secondary HD vascular access following the initial failed forearm access is unknown, yet is critical in order to continue receiving life-sustaining haemodialysis therapy. A trial is needed to help define the balance between access complications, interventions to manage them and related patient morbidities in order to determine the "next best access".

This current protocol is a pilot study for a larger study of the same design.

As of 12/03/2010 this record was updated to include further details on the Canadian Institutes of Health Research funded pilot study (an extension of the pilot study registered here). All details can be found under the relevant fields with the above update date. Please note that due to this extension, the anticipated end date of this trial has been extended; the initial anticipated end date of this trial was 01/08/2010. At this time, the target number of participants was also increased from 38 to 50 participants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Health Network Research Ethics Board approved on the 24th July 2008 (ref: 08-0569-BE)

Study design
Multicentre single-blinded randomised controlled pilot trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
End stage renal disease (ESRD), haemodialysis

Interventions
For this study the trial intervention will be the surgical creation, by a qualified participating surgeon, and guideline recommended follow-up management of either an AVF or AV-graft in the upper arm of eligible patients. The duration of the surgery for these procedures can vary case by case, therefore there is no set duration of the treatment. The total duration of follow-up is 18 months.

Added as of 12/03/2010:
Patient questionnaires are to be completed at 3 months and 12 months during the study.

Subjects will be stratified to:
1. Surgeon
2. Reason for first access loss
3. FTM score

The changes have been made to the stratification variables due to limited resources available for vessel mapping on ALL subjects. There would be a potential for delayed patient care if it were necessary to wait for vessel mapping results prior to the randomisation process and access creation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Current information as of 01/07/2010:
The complication-free vascular access days over 18 months from the date of access creation in patients who receive an upper arm VA after a failed forearm access (fistula).

A complication includes any of the following
1. VA related:
1.1. Serious event (thrombosis, radiological or surgical intervention to facilitate or maintain patency, infection/sepsis, mortality (e.g. AVF rupture and exsanguinations)
1.2. VA related bleeding
1.3. VA-related hospitalisation
2. Non-VA related:
2.1. Death from any cause
2.2. Cardiac event
2.3. Cerebrovascular event
2.4. Congestive heart failure

Previous information (prior to 01/07/2010):
The time to first serious vascular event in patients who receive an upper arm arteriovenous fistula compared with an upper arm AV-graft, after a failed forearm access.

Primary and secondary endpoints will be measured on an ongoing basis during the 18 month follow-up phase. Visits to assess for these endpoints will be conducted on a weekly basis. An analysis of all documented endpoints will occur following the 18 month follow-up phase.

Added as of 12/03/2010:
While the true VA cumulative patency would be ideal, it is not feasible as many accesses can remain patent for greater than 5 years. This would place a burden on resources and limit the ability to conduct other clinical studies in the HD population. Therefore, the primary outcome was changed in the CIHR-funded trial to:

The complication-free vascular access days over 18 months from the date of access creation in patients who receive an upper arm VA after a failed forearm access (fistula).

A complication includes any of the following
1. VA related:
1.1. Serious event (thrombosis, radiological or surgical intervention to facilitate or maintain patency, infection/sepsis, mortality (e.g. AVF rupture and exsanguinations)
1.2. VA related bleeding
1.3. VA-related hospitalisation
2. Non-VA related:
2.1. Death from any cause
2.2. Cardiac event
2.3. Cerebrovascular event
2.4. Congestive heart failure

Key secondary outcome(s))
1. Primary patency rates
2. The rates and proportion of interventions required to maintain patency. Rates will be expressed as number of radiological and surgical interventions per access, per access-year, per 1000 access days. This variety will allow comparison of results in the literature.
3. Complication rates:
3.1. Catheter use, its duration (CVC days), and associated complications (such as bleeding, sepsis, hospitalisations)
3.2. Complications directly related to access e.g. infections, central stenosis
3.3. All cause mortality
3.4. Direct VA-related mortality
4. The time to:
4.1. First thrombosis, and
4.2. First radiological or surgical intervention
5. The incidence of primary failure
6. Maximal study cumulative patency: a subset of patients will be followed beyond 18 months until the study has been completed by the last enrolled patient

Primary and secondary endpoints will be measured on an ongoing basis during the 18 month follow-up phase. Visits to assess for these endpoints will be conducted on a weekly basis. An analysis of all documented endpoints will occur following the 18 month follow-up phase.

Completion date
01/08/2011

Eligibility

Key inclusion criteria
1. Patients requiring chronic HD who have already failed a forearm permanent access (AVF or AV-graft) or who require another permanent VA for HD

2. Considered suitable for an upper arm AVF
3. Aged greater than 18 years old, either sex
4. Presence of irreversible chronic renal failure requiring haemodialyisis
5. Three times weekly dialysis
6. Must have vessels deemed suitable for creation of an AVF according to the surgeon and must include at least two of the following features:
6.1. Visible length of at least 4 - 6 cm on physical exam, dependent on patient size (with or without augmentation)
6.2. Palpable length of at least 4 - 6 cm on physical exam, dependent on patient size (with or without augmentation)
7. Straight vessel segment

Added as of 12/03/2010:
The eligibility criteria of the CIHR-funded pilot study includes the following:
8. Inclusion of subjects whose forearm is not a viable site for a first access creation therefore the "first" access is an upper arm access meaning the non-viable forearm site would be considered a "failed" access site for the purposes of the study
9. Inclusion of subjects who are eligible and meet the inclusion/exclusion criteria but refuse the randomisation process of the study
10. Inclusion of subjects that are deemed eligible for study participation by the attending nephrologists or investigator and meet all inclusion/exclusion criteria as per the protocol however the surgeon refuses patient randomisation
11. Inclusion of subjects who are deemed eligible by the attending nephrologists or investigator and surgeon but decline having any access created and continue to use a catheter for haemodialysis treatment

*note that subjects enrolled into the study who meet the eligibility criteria #9 through #12 will be followed as "non-randomised" study subjects

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Acute renal failure, likely to be reversible with recovery of renal function
2. Involvement in another interventional access study
3. Expected life expectancy less than six months (e.g. due to active malignancy; serious comorbidity such as hepatic failure)
4. Patients who have not yet initiated dialysis
5. Allergies to contrast

Added as of 12/03/2010:
The eligibility criteria of the CIHR-funded pilot study includes the following:
6. Exclusion of patients receiving more than 4 times per week haemodialysis treatment

Date of first enrolment
01/08/2008

Date of final enrolment
01/08/2011

Locations

Countries of recruitment
Canada

Study participating centre
Toronto General Hospital
Toronto
Canada
M5G 2C4

Sponsor information

Organisation
Toronto General Hospital Research Institute (Canada)

ROR
https://ror.org/026pg9j08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Health Network - Toronto General Hospital (Canada) - Internally funded by lead principal investigator

Funder Name

Added 12/03/2010:

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-98663)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration