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Pilot randomised trial comparing the effect of different strengths of an antiseptic solution, chlorhexidine gluconate, on central venous catheter related infections in haemodialysis patients in three outpatient haemodialysis centres

Submission date
05/08/2010

Recruitment status
No longer recruiting

Registration date
31/08/2010

Overall study status
Completed

Last Edited
17/01/2019

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EudraCT number 2010-019984-12; Sponsors Protocol Code Number Prot-AMNCH-TCD-CHG-1-2010/

Study information

Scientific Title
A multicentre randomised trial comparing the effects of 2% chlorhexidine gluconate in 70% isopropyl alcohol as a skin, exit site and catheter hub cleansing agent versus other forms of chlorhexidine gluconate which are in routine use, on central venous catheter-related infections in haemodialysis patients

Acronym
CHG Trial

Study objectives
There is no difference between 2% chlorhexidine gluconate in 70% alcohol and 0.05% aqueous chlorhexidine gluconate or 0.5% chlorhexidine gluconate in 70% alcohol in the reduction of central venous catheter (CVC) related infections in haemodialysis patients.

Please note that as of 21/01/2013, the following changes were made to the trial record:
1. The anticipated start date was updated from 01/09/2010 to 18/10/2010
2. The anticipated end date was updated from 05/09/2012 to 14/09/2012

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Approval was granted by the Joint St. James Hospital and Adelaide and Meath Hospital, incorporating The National Children's Hospital Research Ethics Committee, on the 12th of July 2010 (ref: 2010/27/03)

Study design
Multicentre open label pilot multicentre randomised trial using a 1:1 randomisation ratio

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
End stage renal disease; haemodialysis; central venous catheter infections

Interventions
All patients assigned to the 'experimental' group will receive 2% chlorhexidine gluconate in 70% alcohol cutaneous solution. Those patients assigned to the 'control' group will receive the chlorhexidine gluconate cutaneous solution that is the standard antiseptic agent used in the routine care of their CVC. There are two different types of routine care in use in the centres that will participate in the randomised trial: 0.5% chlorhexidine gluconate in 70% alcohol and 0.05% aqueous chlorhexidine gluconate. Patients whose routine care is 0.5% chlorhexidine gluconate in 70% alcohol will be randomised to receive either the experimental intervention of 2% chlorhexidine gluconate in 70% alcohol or the routine care of 0.5% chlorhexidine gluconate in 70% alcohol. Similarly, patients whose routine care is 0.05% aqueous chlorhexidine gluconate will be randomised to receive either the experimental intervention of 2% chlorhexidine gluconate in 70% alcohol or routine care of 0.05% aqueous chlorhexidine gluconate.

1. The experimental group will receive 2% chlorhexidine gluconate in 70% alcohol antiseptic cleansing agents in the form of:
1.1. ChloraPrep® with Tint 2% w/v/70%v/v cutaneous solution (3ml applicator) will be used to cleanse the skin and exit site of the central venous catheter when the catheter dressing is changed.
Duration of treatment: Subjects will receive this intervention every time the dressing is changed for a period of 12 months. Frequency of dressing change will be determined by local policy.
1.2. Sani Cloth CHG 2% medical device wipe will be used to cleanse the hubs of central venous catheters when connecting or disconnecting patients from dialysis.
Duration of treatment: every dialysis session (three times a week) for a period of 12 months

2. Patients allocated to the 'control' group will receive either:
2.1. 0.5% chlorhexidine gluconate in 70% alcohol cutaneous solution (Hydrex Pink) or
2.2. 0.05% aqueous chlorhexidine gluconate cutaneous solution (Unisept)
Duration of treatment will be 12 months. Control intervention will be used to cleanse the catheter hubs when connecting and disconnecting patients from dialysis (three times a week) for a period of 12 months. Control intervention will also be used when skin and exit site are cleansed every time the catheter dressing is changed for a period of 12 months. Frequency of dressing change will be determined by local policy.

Recruitment will take place over an eight month period. Each patient will be followed up for 12 months. Data capture will be completed in 20 months from the recruitment of the first patient. Patients who develop CVC-associated or related bloodstream infection will be withdrawn from the study.

Chief Investigator & Research Sponsor:
Dr George Mellotte
Department of Nephrology Adelaide & Meath Hospital, incorporating The National Children's Hospital
Tallaght
Dublin 24

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
CVC-related infections:
1. Catheter-associated bloodstream infections
2. Catheter-related bloodstreams infection
3. Local access infection

Case definitions used in the trial protocol will be those set down by the Infectious Disease Society of America and the Centre for Disease Control and Disease.

Secondary outcome measures
1. Time to development of first CVC-related infection
2. Patient mortality secondary to infection
3. CVC-related infection rates according to causative organism
4. Time to infection associated catheter removal
5. Episodes of hospitalisation
6. Incidence of adverse reactions
7. Economic Cost
8. Incidence and prevalence of arteriovenous fistula (AVF), arteriovenous graft (AVG) and CVC use in haemodialysis population

Overall study start date
18/10/2010

Completion date
14/09/2012

Eligibility

Key inclusion criteria
1. Patients over the age of 18 who require haemodialysis for end stage renal disease (ESRD)
2. Patients on long term haemodialysis using permanent tunnelled cuffed CVC
3. Patients whose permanent tunnelled cuffed CVC has been inserted at least four weeks prior to entry into the study (to avoid recruiting patients who may develop infection secondary to insertion technique)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
180 (105 by close of recruitment)

Key exclusion criteria
1. Patients whose CVC is used for purposes other than access for haemodialysis
2. Patients with a known allergy to any component of the interventions
3. Patients whose CVC material is not compatible with interventions
4. Patients who are using central venous catheters or dressings which are not standard practice for the unit
5. Patients who are unable to give informed consent

Date of first enrolment
18/10/2010

Date of final enrolment
14/09/2012

Locations

Countries of recruitment
Ireland

Study participating centre
School of Nursing and Midwifery
Dublin
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Dublin 2

Sponsor information

Organisation
Trinity College Dublin (Ireland)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02tyrky19

Funder(s)

Funder type
University/education

Funder Name
Trinity College Dublin (Ireland) - School of Nursing and Midwifery

Funder Name
Carefusion Ltd & PDI (Ireland) - providing ChloraPrep® with Tint applicator and Sani-Cloth CHG 2% (These companies will have no influence over the conduct, analysis or reporting of the study)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	01/08/2016	17/01/2019	Yes	No