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Antibiotic-lock technique with Taurolidine for prevention of central venous catheter infection in neutropenic patients

Submission date
09/09/2015

Recruitment status
No longer recruiting

Registration date
21/10/2015

Overall study status
Completed

Last Edited
25/02/2021

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
A central venous catheter (CVC) is a long, thin tube that is inserted into the major vein in the neck (jugular vein), chest (subclavian vein or axillary vein) or groin (femoral vein). CVC's are considered to be one of the best ways to give long-term medicine treatment, such as chemotherapy. The use of CVC's has increased considerably in recent years and catheter-related bloodstream infections (CR-BSI) have become a recurrent complication. These infections can cause seriously ill patients with CVC's to become even more ill or even die. A good way of preventing these infections is by "flushing" the tube with an antibacterial solution, which helps to create a barrier at the catheter site so that harmful bacteria cannot get into the blood (catheter lock solution). This is especially important for patients who have low levels of certain white blood cells in their blood (neutropenia), and are therefore more susceptible to infections. Taurolidine-citrate is an antibiotic which has been shown to be very effective in fighting CR-BSI's when used as a catheter lock solution. The aim of this study is to see whether using a Tautolidine-lock solution is an effective way of preventing CR-BSI's in neutropenic patients.

Who can participate?
Adults in hospital, who have a central venous catheter and are likely to develop neutropenia lasting for more than one week.

What does the study involve?
Participants are randomly allocated into one of two groups. The first group (intervention group) is given a 2.5ml solution of 2% Taurolidine-citrate three times a week, and the second group (control group) is given heparin (acting as a placebo as it has no effect on the infection) three times a week. The solution is left in place for one hour (antibiotic-lock technique) for one hour, before it is aspirated (sucked away) with a syringe. Treatment continues until patient recovers from neutropenia; when the catheter needs to be used for continuous medicine treatment; or when the patient dies. Levels of infection at the catheter site or in the blood, throughout the study.

What are the possible benefits and risks of participating?
There are no benefits or risks of participating in this trial.

Where is the study run from?
1. Hospital Universitari de Bellvitge (Spain)
2. Duran i Reynals Hospital – Catalan Institute of Oncology (Spain)

When is the study starting and how long is it expected to run for?
January 2013 to September 2018

Who is funding the study?
The Carlos III Health Institute (Spain)

Who is the main contact?
Dr Carlota Gudiol

Contact information

Type(s)
Scientific

Contact name
Dr Carlota Gudiol

Contact details
Infectious Disease Department
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Feixa Llarga s/n
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08907

Additional identifiers

Protocol serial number
PI13/01474

Study information

Scientific Title
Antibiotic-lock technique with Taurolidine for prevention of central venous catheter infection in neutropenic patients: a randomized, double-blind, placebo-controlled study

Acronym
TAURCAT

Study objectives
Antibiotic-lock technique with Taurolidine would be effective and safe in preventing the bacterial colonization of the central venous catheters in neutropenic patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Hospital Universitari de Bellvitge (Comité Ètic d'Investigació Clínica), 06/06/2013, ref: AC019/13

Study design
Randomised double-blind placebo-controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
1. Catheter infection
2. Catheter-related bacteremia

Interventions
Patients will be randomly assigned to undergo antibiotic-lock technique of the central venous catheter with Taurolidine 3 times a week or with heparin (placebo), during the neutropenic phase. The antibiotic-lock technique of the catheters in both arms will be stopped when the neutrophil count recovers above 500 micro-liters, when the catheter needs to be removed for any reason, when an episode of catheter-related bacteremia occurs, when the catheter needs to be used with a continuous infusion or when the patient dies.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Taurolidine

Primary outcome(s)
Bacterial colonization of at least one of the three hubs of the central venous catheter, measured by the detection of bacterial growth in the hubs, which are cultured 3 times a week, until the end of the intervention.

Key secondary outcome(s))
1. Incidence of catheter-related bacteraemia, measured daily throughout the intervention, using blood cultures when the patient has fever
2. The number of cases where the venous catheter has to be removed for any reason, monitored throughout the intervention period
3. Overall mortality is measured during the intervention period and for 30 days after the end of the intervention in both treatment groups

Completion date
19/05/2018

Eligibility

Key inclusion criteria
1. Adult patients aged > 18 years
2. Hospitalized with leukemia, lymphoma or stem cell transplantation
3. Carry a central venous catheter
4. Likely to develop neutropenia (<500 neutrophils per ul) lasting more than one week

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
150

Key exclusion criteria
1. Patients with a (not flexible) semi-rigid central venous catheter
2. Patients who have been found to have a positive culture of the hubs or the insertion site of the catheter, previously to randomization
3. Patients in whom the central venous catheter is used for parenteral nutrition or medication that needs continuous infusion
4. Patients receiving systemic antibiotic treatment ≥ 48 hours
5. Patients who have an active infection at the baseline statement

Date of first enrolment
15/10/2013

Date of final enrolment
19/04/2018

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitari de Bellvitge
Feixa Llarga
L'Hospitalet de Llobregat
Barcelona
Spain
08907

Study participating centre
Duran i Reynals Hospital – Catalan Institute of Oncology
Gran Via 199-203
L'Hospitalet de Llobregat
Barcelona
Spain
08908

Sponsor information

Organisation
The Carlos III Health Institute (Instituto de Salud Carlos III)

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Instituto de Salud Carlos III

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, La misión del Instituto de Salud Carlos III (ISCIII), ISCIII

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/01/2020	25/02/2021	Yes	No
Protocol article	protocol	02/05/2018		Yes	No