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Will prophylactic antibiotics in out of hospital cardiac arrest survivors receiving targeted temperature management prevent poor outcomes

Submission date
18/01/2017

Recruitment status
No longer recruiting

Registration date
22/02/2017

Overall study status
Completed

Last Edited
30/08/2017

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A cardiac arrest is a serious medical condition in which the heart suddenly stops beating and is a major cause of death in people across all age groups. An out-of-hospital cardiac arrest (OHCA) is where this happens when a person is not in hospital, and is the most common type of cardiac arrest. OHCA patients have low rates of survival to hospital discharge, between 7.9-21.0% in various regions in North America, with a higher likelihood of survival in those with ventricular fibrillation (a heart rhythm abnormality). Targeted temperature management (TTM) is a treatment which works to achieve a specific body temperature for a specific period of time. It has been found to improve neurological (brain and nervous system) outcomes and reduce death rates, and is widely adopted in international guidelines. Although TTM has been found to improve long-term outcomes, recent studies report that it could be related to the development of infections. The aim of this study is to find out whether giving patients antibiotics before they have TTM can reduce rates of infections, time of breathing machines, the length of stay in the intensive care unit and hospital as a whole and death rates.

Who can participate?
Adults who have had an out of hospital cardiac arrest who are suitable for treatment with TTM.

What does the study involve?
All participants receive standard care for out of hospital cardiac arrest management while they are in hospital, including heart monitoring, help with breathing using a breathing machine and TTM. Participants are randomly allocated to one of two groups. Those in the first group take antibiotics for three days, and those in the second group take a placebo (dummy drug) for three days. Participants in both groups are monitored until they are discharged from hospital and have their medical notes regularly reviewed in order to monitor infections, survival and length of time in hospital.

What are the possible benefits and risks of participating?
Participants may benefit from an improved outcome after their cardiac arrest. There is a small risk of diarrhea from the antibiotics used in this study.

Where is the study run from?
University Health Network (Canada)

When is the study starting and how long is it expected to run for?
February 2016 to December 2021

Who is funding the study?
University Health Network (Canada)

Who is the main contact?
Dr Christopher Overgaard
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
2017-001

Study information

Scientific Title
A randomized controlled study to evaluate the effect of prophylactic antibiotics in the prevention of early CCU complications in post-cardiac arrest survivors receiving targeted temperature management

Study objectives

The aim of this study is to determine if prophylactic antibiotics is associated with a reduction in early post-hospitalization adverse outcomes, in duration of mechanical ventilation, as well as ICU and hospital LOS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Health Network Research Ethics Board, 10/05/2017, ref: 16-5632-B

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Out of hospital cardiac arrest

Interventions
Participants are randomized 1:1 to one of two groups.

Intervention group: Participants receive 3 doses of Ceftriazone every 24 hours. The first dose will be at time of randomization.

Control group: Participants receive 3 doses of placebo (D5W without antibiotics) every 24 hours. The first dose will be at time of randomization.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
1. Incidence of VAP/HAP (within 7 days) is measured using review of patient notes at time of enrollment to 7 days post randomization
2. Incidence of sepsis (within 7 days) is measured using review of patient notes at time of enrollment to 7 days post randomization
3. In-hospital mortality (all cause) is measured using review of patient notes at time of enrollment to day of discharge from hospital

Key secondary outcome(s))

1. CCU LOS (hours) is measured by reviewing patient notes at the time of admission up to time of discharge from CCU
2. Hospital LOS (days) is measured by reviewing patient notes at time of admission up to time of discharge from hospital
3. Neurologic outcome at time of discharge is measured by categorising patients by cerebral performance category, CPC 1-2 or 3-5 at the time of discharge from hospital
4. Complications of antibiotic use (C. difficile, thrush, other nosocomial infection) is measured by reviewing patient notes during their hospital stay
5. Necessity for re-intubation is measured by reviewing patient notes at the time of admission up to discharge from hospitalization

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Age >18 years
2. Out-of-hospital cardiac arrest with ROSC
3. Glasgow coma scale <8 at time of hospital admission
4. Treated with TTM 32-34 degrees Celsius
5. Delay from ROSC to randomization <6 hours
6. Consent from substitute decision maker (SDM)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. In hospital cardiac arrest
2. Ongoing antibiotic use for other infection prior to hospitalization (up to 1 week prior)
3. Diagnosis of pneumonia or sepsis prior to hospitalization
4. Non-cardiac illness that is immediate threat to life (i.e. intracranial hemorrhage, perforated viscus etc.).
5. Pregnancy
6. Known anaphylactic reaction to antibiotic used in study

Date of first enrolment

01/03/2017

Date of final enrolment
01/03/2020

Locations

Countries of recruitment
Canada

Study participating centre
University Health Network
200 Elizabeth St.
Toronto, ON
Canada
M5G 2C4

Sponsor information

Organisation
University Health Network

ROR
https://ror.org/042xt5161

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Health Network

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Chris Overgaard (Chris.Overgaard@uhn.ca)

IPD sharing plan summary

Available on request