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Does the use of the Venner™ PneuX YP™ VAP prevention system reduce the risk of Ventilator Associated Pneumonia (VAP) following major heart surgery

Submission date
22/03/2011

Registration date
22/03/2011

Last Edited
23/05/2017

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Respiratory

[ ] 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

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Additional identifiers

Protocol serial number
9831

Study information

Scientific Title
Does the use of the Venner™ PneuX YP™ VAP prevention system reduce the risk of Ventilator Associated Pneumonia (VAP) following major heart surgery

Acronym
LoVAP

Study objectives
The aim of this trial to determine whether the VennerTM PneuX P.Y.TM VAP prevention system reduces the risk of developing ventilator-associated pneumonia compared to standard endotracheal tubes in high risk patients scheduled for elective major heart surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
10/H1208/42

Study design
Randomised; Interventional; Design type: Prevention, Process of Care

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Cardiovascular, Infection, Respiratory, Generic Health Relevance and Cross Cutting Themes; Subtopic: Cardiovascular (all Subtopics), Infection (all Subtopics), Respiratory (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Cardiovascular, Infectious diseases and microbiology , Respiratory, Critical Care

Interventions
Endotracheal intubation, Standard endotracheal tube VS Venner Pneux YP VAP Preventon system tube; Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Proportion of patients who develop VAP between the two groups; Timepoint(s): Within 48 hours of extubation

Key secondary outcome(s))
Not provided at the time of registration

Completion date
16/08/2011

Eligibility

Key inclusion criteria
1. Male and female patients = 70 years scheduled for elective major heart surgery
2. Patients = 16 years with impaired left ventricular function scheduled for elective major heart surgery. Impaired left ventricular function is defined as left ventricular ejection fraction =49%
Target Gender: Male & Female ; Lower Age Limit 16 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients under 16 years old
2. Patients who present as an emergency for major heart surgery
3. Patients in whom pneumonia is proven or suspected prior to surgery
4. Pregnant patients
5. Patients enrolled in another study
6. Patients who are unable to give written consent

Date of first enrolment
17/01/2011

Date of final enrolment
16/08/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Wolverhampton Road , Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Sponsor information

Organisation
Royal Wolverhampton Hospitals NHS Trust (UK)

ROR
https://ror.org/05pjd0m90

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration