

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/03/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/05/2017	Condition category Respiratory	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 Venner™ PneuX P.Y.™ 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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

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 measure

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

Secondary outcome measures

Not provided at the time of registration

Overall study start date

17/01/2011

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 $\leq 49\%$
- Target Gender: Male & Female ; Lower Age Limit 16 years

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 240; UK Sample Size: 240

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

England

United Kingdom

Study participating centre

Wolverhampton Road , Heath Town

Wolverhampton

United Kingdom

WV10 0QP

Sponsor information

Organisation

Royal Wolverhampton Hospitals NHS Trust (UK)

Sponsor details

Royal Wolverhampton NHS Trust, New Cross Hospital

Wolverhampton

England

United Kingdom

WV10 0QP

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/05pjd0m90>

Funder(s)

Funder type

Government

Funder Name

Department of Health (UK)

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