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The haemodynamic effect of sildenafil in mechanically ventilated patients with secondary pulmonary hypertension and ensuing right ventricular failure necessitating the administration of dobutamine

Submission date
09/09/2010

Recruitment status
No longer recruiting

Registration date
23/09/2010

Overall study status
Completed

Last Edited
03/04/2014

Condition category
Circulatory System

[_] 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

Protocol serial number
2010/ICU/sildenafil01trial

Study information

Scientific Title
The haemodynamic effect of sildenafil in mechanically ventilated patients with secondary pulmonary hypertension and ensuing right ventricular failure necessitating the administration of dobutamine: a non-randomised non-controlled single arm interventional trial

Study objectives
We assessed the response of the right ventricular (RV) function following treatment with sildenafil in mechanically ventilated patients with secondary pulmonary hypertension group III according to World Health Organization (WHO) classification, and ensuing RV failure necessitating the administration of dobutamine. We examined whether the administration of sildenafil could acutely alter RV function, thus facilitating weaning from dobutamine and subsequently weaning from mechanical ventilation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Committee of the General State Hospital of Athens approved on the 1st January 2007

Primary study design
Interventional

Study design
Non-randomised non-controlled single arm interventional trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Secondary pulmonary hypertension, right ventricular failure

Interventions
The design of the study included measurements of various haemodynamic parameters by means of invasive Swan Ganz method and of various echocardiographic parameters by means of echocardiography in all phases of the study.

In phase 1 (day 1), dobutabine was infused (5 μg/kg/min) in 12 patients. On day-2, sildenafil was administered (80 mg/day). Thereafter, weaning from dobutamine was attempted (phase 2: days 2 - 15). Patients who tolerated sildenafil and successfully weaned from dobutamine were considered responders and the rest non-responders (sildenafil stopped). In phase 3 (days 16 - 20) weaning from ventilator was attempted. Echocardiographic, haemodynamic and cGMP measurements were conducted repeatedly, at baseline, phase 1, phase 2 and phase 3 of the study.

Total duration of treatment and follow-up = 20 days.

Intervention Type

Drug

Phase
Not Applicable

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

Primary outcome(s)
Invasive and non-invasive cardiovascular parameters:
1. Cardiac index
2. Right ventricular fractional area change
3. Pulmonary vascular resistance and systemic vascular resistance indices
4. Right and left ventricular stroke work indices

All measured at each of the phases.

Key secondary outcome(s)
1. Measurements of possible improvements in oxygenation and haemodynamic conditions by means of mixed venous oxygen saturation and PO2 to FIO2 ratio
2. Success of weaning from mechanical ventilation

All measured at each of the phases.

Completion date
01/04/2010

Eligibility

Key inclusion criteria
1. Secondary pulmonary arterial hypertension (PAH) associated with disorders of the respiratory system or hypoxemia (WHO Group III PAH). PAH was documented by the following echocardiographic criteria:
1.1. Increased systolic pulmonary artery pressure greater than 37 mmHg (using the Doppler-derived tricuspid regurgitation velocity)
1.2. Dilatation of the right cardiac chambers
1.3. Hypertrophy of the RV free wall
1.4. Left sided transposition of the interventricular septum and D-shape derangement of the left ventricle
2. Required mechanical ventilation
3. Admitted to the intensive care unit (ICU) from January 2007 to April 2010
4. Decreased cardiac output necessitating the administration of inotropes. Cardiac output was estimated by Doppler echocardiography at the aortic annular plane.
5. Aged 48 - 65 years, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Secondary PAH due to left ventricular (LV) failure, and/or other causes of secondary PAH
2. Patients exhibited, upon admission, acute respiratory distress syndrome (ARDS) and septic shock
3. Hemodynamically unstable, necessitating administration of any other vasoactive medication during the study period

Date of first enrolment
01/01/2007

Date of final enrolment
01/04/2010

Locations

Countries of recruitment
Greece

Study participating centre
Intensive Care Unit
Athens
Greece
14127

Sponsor information

Organisation
General State Hospital of Athens (Greece)

ROR
https://ror.org/00zq17821

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
General State Hospital of Athens (Greece)

Results and Publications

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	10/08/2013		Yes	No