

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/09/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/04/2014	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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

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

Study design

Non-randomised non-controlled single arm interventional trial

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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), dobutamine 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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/01/2007

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

Age group

Adult

Sex

Both

Target number of participants

12 patients

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)

Sponsor details

c/o Andreas Karabinis
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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00zq17821>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

General State Hospital of Athens (Greece)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[Results article](#)

results

10/08/2013

Yes

No