

Effect of furosemide versus placebo on quality of life in hypertensive patients with pulmonary edema

Submission date 28/03/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/08/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 08/01/2021	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Wolfgang Schreiber

Contact details
Waehringer Guertel 18-20/6D
Vienna
Austria
1090

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Effect of furosemide versus placebo on quality of life in hypertensive patients with pulmonary edema

Study objectives

In patients with hypertensive pulmonary edema there is no difference in the Borg rating of perceived exertion (BORG scale) one hour after hospital admission between furosemid and placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval from ethics commission of Stadt Wien on 28/03/2006.

Study design

Randomised, double-blind, placebo-controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Hypertensive pulmonary edema

Interventions

Intravenous furosemide versus intravenous placebo on top of standard medication.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Furosemide

Primary outcome measure

Changes in dyspnoea severity one hour after hospital admission (BORG scale).

Secondary outcome measures

1. BORG scale at hours two, three and six
2. Visual analogue scale score at one, two, three and six hours
3. Blood pressure
4. Partial pressure of oxygen in arterial blood (paO₂), partial pressure of carbon dioxide in arterial blood (paCO₂), spot oxygen saturation (SpO₂)
5. pH, BE, lactate
6. Safety: acute myocardial infarction, hypotension, intubation, catecholamines, cardiac arrest, death

Overall study start date

01/05/2006

Completion date

30/11/2007

Eligibility

Key inclusion criteria

1. Hypertensive pulmonary edema (Relative Risk [RR] more than 180 mmHg, crackles in auscultation)
2. Over 18 years of age

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60

Total final enrolment

59

Key exclusion criteria

1. Women of childbearing potential
2. Chronic renal failure with renal replacement therapy
3. Acute ST-Elevation Myocardial Infarction (STEMI)
4. Need for intubation on arrival at scene
5. Need for catecholamines on arrival
6. Known incompatibilities to furosemide, urapidil or morphine hydrochloride

Date of first enrolment

01/05/2006

Date of final enrolment

30/11/2007

Locations

Countries of recruitment

Austria

Study participating centre

Waehringer Guertel 18-20/6D

Vienna

Austria

1090

Sponsor information

Organisation

Medical University of Vienna (Austria)

Sponsor details

Department of Emergency Medicine

Waehringer Guertel 18-20/6D

Vienna

Austria

1090

Sponsor type

University/education

Website

<http://www.meduniwien.ac.at/>

ROR

<https://ror.org/05n3x4p02>

Funder(s)

Funder type

University/education

Funder Name

Medical University of Vienna, Department of Emergency Medicine

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?
Results article	results	01/06/2011	08/01/2021	Yes	No