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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/08/2006	**Overall study status** Completed	
Last Edited 08/01/2021	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Contact details
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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