

Cutaneous vascular reactivity and flow motion response to vasopressin in advanced vasodilatory shock and severe postoperative multiple organ dysfunction syndrome

Submission date
14/10/2005

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
21/10/2005

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
17/09/2007

Condition category
Injury, Occupational Diseases, Poisoning

Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Guenter Luckner

Contact details

Anichstrasse 35
Innsbruck
Austria
6020

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

The effects of a supplementary Arginine-Vasopressin (AVP) infusion on microcirculation in advanced vasodilatory shock and postoperative multiple organ dysfunction syndrome are unknown.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

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

Severe multiple organ dysfunction syndrome

Interventions

NE plus supplementary AVP (Pitressin®; Pfizer, Karlsruhe, Germany) infused at a continuous rate of 4 IU/hour versus NE alone.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Arginine-Vasopressin (AVP)

Primary outcome measure

Differences in the area under the concentration-time Area Under Curve (AUC) of the Doppler signal and the reactive hyperemic response to forearm ischaemia between AVP/NE and NE patients.

Secondary outcome measures

Differences in the oscillation frequency of the Doppler signal between groups.

Overall study start date

01/01/2004

Completion date

31/12/2004

Eligibility

Key inclusion criteria

Critically ill patients suffering of severe multiple organ dysfunction syndrome after cardiac or major surgery with a mean arterial blood pressure less than 65 mmHg despite adequate volume resuscitation, and Norepinephrine (NE) requirements greater than 0.5 µg/kg/min.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

18

Key exclusion criteria

Patients with arterial vascular occlusive disease or insulin-dependent diabetes mellitus.

Date of first enrolment

01/01/2004

Date of final enrolment

31/12/2004

Locations

Countries of recruitment

Austria

Study participating centre

Anichstrasse 35
Innsbruck
Austria
6020

Sponsor information

Organisation

Innsbruck Medical University (Austria)

Sponsor details

Christoph-Probst-Platz
Innrain 52
Innsbruck
Austria
6020

Sponsor type

University/education

Website

<http://www.i-med.ac.at>

ROR

<https://ror.org/03pt86f80>

Funder(s)

Funder type

University/education

Funder Name

Innsbruck Medical University (Austria)

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	01/01/2006		Yes	No