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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

Registration date
21/10/2005

Overall study status
Completed

Last Edited
17/09/2007

Condition category
Injury, Occupational Diseases, Poisoning

[_] 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

Contact name
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Anichstrasse 35
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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