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Blood flow change in the forearm after treatment of severely ill non-diabetic patients with insulin infusion

Submission date 02/07/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/07/2009	**Overall study status** Completed	
Last Edited 04/05/2010	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Intensive insulin treatment in critically ill patients and forearm blood flow: a randomised parallel group trial

Study objectives
Intensive treatment of critically ill patients with insulin to the range of serum glucose concentrations between 4.4 mmol/l and 6.1 mmol/l decreased the mortality rate in the group of patients treated at the department of intensive care following an operative procedure, while in medical patients such treatment had a favourable effect on the occurrence and degree of vital organ failures and the length of artificial ventilation. The mechanisms of insulins positive effects are not clear. The purpose of this research was to test the hypothesis that positive effect of intensive insulin treatment are related to blood flow in different organs including the forearm in artificially ventilated septic patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee at the Ministry of Health of Republic of Slovenia approved on the 14th May 2002 (ref: 88/05/02)

Study design
Single centre interventional parallel group randomised trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mechanical ventilation due to acute respiratory failure

Interventions
Patients were randomised into two groups as regards the regulation of blood glucose: intensive (Group 1) and standard (Group 2). In the standard protocol the serum glucose concentration was maintained within the range of 7.0 - 11.0 mmol/l while in the intensive protocol the concentration was maintained within the range of 4.4 - 6.1 mmol/l.

In a 50 ml syringe, 50 IE of human insulin for intravenous administration was diluted in a 0.9% solution of sodium chloride. The amount of infusion was adjusted according to the values of serum glucose concentrations according to a study published by Brown and Dodek (2001). The serum glucose concentration was determined with the hexokinase method hourly at the beginning of insulin treatment and every 2 hours thereafter, except when the dose of insulin was adjusted. In this case, the next measurement was taken after 1 hour.

The treatment was initiated within 48 hours from the start of artificial ventilation. Up to that point, the serum glucose concentrations were maintained in the 8.8 - 11.0 mmol/l range by means of subcutaneous administration of rapid-acting insulin or the above described infusion. Blood glucose levels were maintained according to different protocols for 72 hours from the start of the trial.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Insulin

Primary outcome(s)
1. Measurements of forearm flow, performed by means of a plethysmograph (model EC5R, D.E. Hokanson, Inc., USA). In brief outline: the patient was in a supine position with the upper body lifted by approximately 150 cm. The forearm was positioned in the level of the right atrium (at 3 /5 chest height). A 10 cm wide cuff was placed on the forearm and connected to the rapid cuff inflator. A mercury-filled clamp with a circumference 1.5 - 2 cm smaller than the forearm circumference was placed on the widest part of the forearm. A second, 8 cm wide cuff was placed just above the wrist in order to block arterial inflow to the thermoregulatory area, in our case the hand. The upper arm cuff pressure was preset to 50 mmHg. After 10 seconds of inflation the cuff was deflated for 5 seconds. Prior to the measurement, the wrist cuff was inflated to the value 40 mmHg above the systolic pressure for the duration of a single measurement (approximately 1 minute). The plethysmographic curve was recorded and measurement was repeated every 10 minutes, and each individual measurement lasted 1 hour.
2. Instantaneous arterial flow, calculated manually by analysing the average value of three plethysmographic recordings
3. Values of instantaneous arterial flow, expressed as ml/100 ml of tissue/min. To estimate the total forearm flow the area under the 60-minute arterial flow curve was calculated. All arterial flow measurements were taken at the beginning of the study (t0), after 2 hours (t1), after 24 hours (t2) and after 72 hours (t3) between 8 am and 9 am, with the exception of insulin infusion measurements, which were taken between 11 am and 12 pm.

Key secondary outcome(s))
1. Duration of mechanical ventilation (days)
2. 30-day mortality rate

Completion date
31/12/2006

Eligibility

Key inclusion criteria
Critically ill mechanically ventilated patients of both sexes, aged 18 years and older, who meet following criteria:
1. Admission criteria for sepsis (at least two American College of Chest Physicians/Society of Critical Care Medicine [ACCP/SCCM] 1992 criteria)
2. Mechanical ventilation due to acute respiratory failure
3. No prior data of diabetes mellitus
4. Start of the trial up to 48 hours after admission

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Aged below 18 years
2. Pregnancy
3. Terminal neoplastic disease
4. Known diabetes mellitus
5. Mechanical ventilation due to due to primary failure of respiratory muscles
6. Mechanical ventilation due to brain injury

Date of first enrolment
01/01/2005

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Slovenia

Study participating centre
General Hospital Celje
Celje
Slovenia
3000

Sponsor information

Organisation
General Hospital Celje (Slovenia)

ROR
https://ror.org/03psk2k71

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
General Hospital Celje (Slovenia) - Department for Education and Research

Results and Publications

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	01/01/2009		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes