

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

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>02/07/2009   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>29/07/2009 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>04/05/2010       | <b>Condition category</b><br>Respiratory          | <input type="checkbox"/> Individual participant data                                              |

**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 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/01/2009   |            | Yes            | No              |