

# Recombinant human erythropoietin therapy in critically ill patients: a dose response study

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<b>Registration date</b> 16/06/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/01/2021	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

## Study information

**Scientific Title**  
Recombinant human erythropoietin therapy in critically ill patients: a dose response study

**Study objectives**  
The aim of our study was to assess the efficacy of two dosing schedules of recombinant human erythropoietin (rHuEPO) in increasing haematocrit (Hct) and haemoglobin (Hb) and reducing the exposure to allogeneic red blood cells (RBC) transfusion in critically ill patients.

**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

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Critically ill patients with anaemia

**Interventions**

Patients were randomly assigned to receive:

1. Intravenous (i.v.) iron saccharate alone (control group)
2. i.v. iron saccharate and subcutaneous recombinant human erythropoietin (rHuEPO) 40,000 units once per week (Group A)
3. i.v. iron saccharate and subcutaneous rHuEPO 40,000 units three times per week (Group B)

rHuEPO was given for a minimum of 2 weeks or until ICU discharge or death. The maximum duration of therapy was 3 weeks.

**Intervention Type**

Drug

**Phase**

Not Specified

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

Recombinant human erythropoietin (rHuEPO)

**Primary outcome(s)**

The primary outcome end-points were:

1. Differences in Hct and Hb between groups
2. Transfusion independence between study day 1 and 28

**Key secondary outcome(s)**

Additional data recorded included:

1. ICU length of stay
2. Cumulative mortality through day 28
3. Adverse effects, assessed daily

**Completion date**

31/12/2003

# Eligibility

## Key inclusion criteria

All patients admitted to the intensive care unit (ICU) in each of the 13 participating centres were evaluated for study eligibility. Inclusion criteria were:

1. Age at least 18 years
2. Hb less than 12 g/dl
3. No iron deficiency defined as transferrin saturation less than 10% and ferritin less than 50 ng/ml
4. Negative pregnancy test (for females in the reproductive age)
5. An expected ICU stay of at least 7 days
6. Provision of signed informed consent

The expected duration of the ICU stay was judged on clinical grounds and APACHE II score by the ICU team at admittance to the unit.

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

All

## Total final enrolment

148

## Key exclusion criteria

1. Chronic renal failure requiring dialysis
2. New onset (less than 6 months) seizures
3. Life expectancy of less than 7 days
4. Previous use of rHuEPO (within 3 months)
5. Recent use of cytostatics or recent radiotherapy (within 1 month)
6. Participation in another research protocol

## Date of first enrolment

01/11/2000

## Date of final enrolment

31/12/2003

# Locations

## Countries of recruitment

Greece

## Study participating centre

ICU, University Hospital of Heraklion

Heraklion

Greece

711 10

## Sponsor information

### Organisation

Janssen-Cilag (Greece)

## Funder(s)

### Funder type

Industry

### Funder Name

Janssen-Cilag (Greece)

## 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	05/10/2005	07/01/2021	Yes	No