

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

Submission date 16/06/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/06/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 07/01/2021	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Dimitris Georgopoulos

Contact details
ICU, University Hospital of Heraklion
Heraklion
Greece
711 10
-
georgop@med.uoc.gr

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**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 measure

The primary outcome end-points were:

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

Secondary outcome measures

Additional data recorded included:

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

Overall study start date

01/11/2000

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

148

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)

Sponsor details

L. Hrinis 56

Athens

Greece

151 21

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lspirou@jacgr.jnj.com

Sponsor type

Industry

Funder(s)

Funder type

Industry

Funder Name

Janssen-Cilag (Greece)

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