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

Submission date
16/06/2005

Recruitment status
No longer recruiting

Registration date
16/06/2005

Overall study status
Completed

Last Edited
07/01/2021

Condition category
Haematological Disorders

[ ] 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

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Additional identifiers

Protocol serial number
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

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?

Results article	results	05/10/2005	07/01/2021	Yes	No