

A double-blind, placebo controlled study to assess the effects of early intervention and/or treatment with epoetin alfa on anaemia in cancer patients receiving non-platinum containing chemotherapy

Submission date 19/08/2002	Recruitment status No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 19/08/2002	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 19/02/2014	Condition category Haematological Disorders	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

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Additional identifiers

Protocol serial number

GN308

Study information

Scientific Title

Study objectives

Not provided at time of registration

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

Anaemia

Interventions

Patients are randomised to one of two treatment arms:

1. Arm A: Patients receive 150 IU/Kg of Epoetin alpha
2. Arm B: Patients receive matching placebo

Epoetin alpha or placebo is given subcutaneously three times per week for the first four weeks (or the first on-study chemotherapy cycle, respectively). Haemoglobin level and/or reticulocyte count will then be used to determine whether the same dose (volume) or a doubled dose (volume) will be used for the remainder of the treatment.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/01/2004

Eligibility

Key inclusion criteria

1. Diagnosis of non-myeloid malignancy, which requires non-platinum containing chemotherapy
2. Predicted chemotherapy of 12 to 24 weeks (three to six cycles) duration
3. Performance score zero to three
4. Life expectancy of more than six months
5. Aged over 18 years
6. Patients with acute leukaemia are excluded
7. No myeloablative chemotherapy
8. No uncontrolled hypertension
9. No evidence of untreated iron, folate or vitamin B12 deficiency

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Does not comply with the above inclusion criteria

Date of first enrolment

01/01/2003

Date of final enrolment

01/01/2004

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Janssen-Cilag Ltd (UK)

ROR

<https://ror.org/03qwpn290>

Funder(s)

Funder type

Industry

Funder Name

Janssen-Cilag Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration