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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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). Haemaglobin 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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Janssen-Cilag Ltd (UK)

Sponsor details
Saunderton
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United Kingdom
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+44 (0)1494 567567

Sponsor type
Industry

Website
http://www.janssen-cilag.co.uk

ROR
https://ror.org/03qwpn290

Funder(s)

Funder type
Industry

Funder Name

Janssen-Cilag Ltd (UK)

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