A randomized, open label, multicentre trial to define the most effective haemoglobin concentration to start erythropoietin beta (neoRecormon) therapy in anaemic subjects with lymphoproliferative malignancy receiving chemotherapy
REPOS Study

Published: 16-10-2006
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To compare the efficacy of erythropoietin beta administered weekly using an early start approach (Hb * 7.2 mmol/l) with standard starting approach (Hb * 6.2 mmol/l) in subjects with lymphoproliferative malignancy, receiving chemotherapy during a 16-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Haematological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON34234

Source
ToetsingOnline

Brief title
Repos study

Condition

- Haematological disorders NEC

Synonym
anemia, malignancy

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: een grant van de fa Roch;leverancier van het middel NeoRecormon,Hoffmann-La Roche

Intervention

Keyword: Anemia, Haemoglobin concentration, lymphoproliferative malignancy, start erythropoietin beta

Outcome measures

Primary outcome

Time to treatment success, defined as increase in Hb * 1,2 mmol/l or a Hb

concentration of * 7,4 mmol/l (without red blood cell transfusion)

Secondary outcome

Incidence of Adverse Events during the treatment period

Changes and abnormalities in laboratory safety parameters

% response at week 12 and 16 (defined as treatment success at 12 weeks and no

subsequent failure i.e. haemoglobin decrease below 7.2 mmol/l)

Rate of increase in haemoglobin

Number of RBC units transfused

QoL (FACT- An and VAS)

Study description

Background summary

Evidence is growing that the use of erythropoietin in patients treated with chemotherapy for solid (and haematological) malignancies may have positive effects on the number of red cell units that have to be transfused and the quality of life. However, until now the vast majority of studied patients were anaemic (Hb generally < 6.8 mmol/l) at the start of erythropoietin administration. It is therefore unknown at which blood haemoglobin concentration administration of erythropoietin should be started, in order to achieve optimal increase in Hb and reduction of red blood cell transfusions; already at the low-normal Hb level (Hb 7.2 mmol/l), or near the level of indication for red blood cell transfusion (6.2 mmol/l).
Preventing a Hb-decline by starting erythropoietin treatment in the range above the ASCO/ASH guidelines for the use of erythropoietin, i.e. above 6.2 mmol/l [60], may lead to a better effect in patients suffering chemotherapy-induced anaemia.
This study will assess a comparison of the clinical outcomes following early initiation of NeoRecormon® 30 000 IU once a week (Hb < 7.2 mmol/l) versus late initiation (Hb < 6.2 mmol/l) in adult, anaemic patients with lymphoproliferative malignancy and the overall safety of NeoRecormon® 30 000 IU once a week.

Study objective

To compare the efficacy of erythropoietin beta administered weekly using an early start approach (Hb * 7.2 mmol/l) with standard starting approach (Hb * 6.2 mmol/l) in subjects with lymphoproliferative malignancy, receiving chemotherapy during a 16-week treatment phase, , ,measured by an increase in haemoglobin * 1.2 moll/l or a haemoglobin concentration * 7.4 mmol/l (without red blood cell transfusion).

Study design

Open label, randomized, multi centre trial

Intervention

To compare the efficacy of erythropoietin beta administered weekly using an early start approach (Hb * 7.2 mmol/l) with standard starting approach (Hb * 6.2 mmol/l) in subjects with lymphoproliferative malignancy, receiving chemotherapy during a 16-week treatment phase, measured by an increase in haemoglobin * 1.2 moll/l or a haemoglobin concentration * 7.4 mmol/l (without red blood cell transfusion).

Study burden and risks

The treatment phase with erythropoietin beta is 16 weeks. During this period patient will visit the outpatient clinic every 4 weeks at the same time

chemotherapy is administrated.
Normal routine blood samples will betaken. Quality of Life questionnaires will be filed out 3 times during this period
The benefit of treatment with NeoRecormon is improvement of quality of life during the period of chemotherapy.
Adverse events of NeoRecormon such as hypertension and trombosis are rare and always reversible.
Adverse events of red blood cell transfusion are eg allergic reactions, anti body formation and transmission of infections (eg HIV and hepatitis) could be irreversible.

Contacts

Public
HagaZiekenhuis

Postbus 40551
2504 LN
Nederland
Scientific
HagaZiekenhuis

Postbus 40551
2504 LN
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with lymphoproliferative malignancy i.e. multipel myeloma, chronic lymphocytic leukemia, non hodgkins lymphoma and hodgkins lymphoma who will be treated with chemotherapy which may induce anaemia

Exclusion criteria

transfusions or red bloodcells during the 2 weeks immediately prior to randomisation or rHuEPO within 12 weeks before inclusion

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2008
Enrollment:	150
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	NeoRecormon
Generic name:	Erythropoeitin Beta

Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	16-10-2006
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	20-05-2008
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-03-2009
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2006-003727-37-NL
CCMO	NL13514.098.06