Clinical trial results:
A prospective, randomized, multicenter study to evaluate the impact of Darbepoetin alfa in combination with Ferric(III)-Carboxymaltose in comparison to Darbepoetin alfa and Ferric(III)-Carboxymaltose alone in patients with breast cancer and chemotherapy-induced anemia

Summary

EudraCT number	2011-001664-22
Trial protocol	AT
Global end of trial date	31 December 2014

Results information

Result version number	v1 (current)
This version publication date	
First version publication date	

Trial information

Trial identification

Sponsor protocol code	2011-001664-22

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Medizinische Universität Wien
Sponsor organisation address	Spitalgasse 23, Vienna, Austria, 1090
Public contact	Abeitlung für Gynäkologie - Senolog, Medizinische Universität Wien - Universitätsklinik für Frauenheilkunde, 0043 14040028010, chrisitan.singer@meduniwien.ac.at
Scientific contact	Abeitlung für Gynäkologie - Senolog, Medizinische Universität Wien - Universitätsklinik für Frauenheilkunde, 0043 14040028010, chrisitan.singer@meduniwien.ac.at

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 December 2014
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	31 December 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To demonstrate treatment efficacy of Darbepoetin alfa and Ferric(III)-Carboxymaltose in comparison to Ferric(III)-Carboxymaltose and Darbepoetin alfa alone in patients with chemotherapy-induced anemia, when given at the last chemotherapy cycle.

Protection of trial subjects:

A signed and dated informed consent must be obtained before any study specific procedures are performed. All hematology and chemistry panels and urine tests will be analyzed at a local laboratory. Procedures that are part of routine care are not considered study specific procedures. Procedures that are part of routine care may be used as screening procedures to determine eligibility. All subjects will be screened for eligibility before randomization. The screening process begins on the date the subject signs the informed consent form and continues until randomization. Only eligible subjects will be enrolled into the study. A subject will be considered enrolled on the day of randomization. Throughout the study, investigators may prescribe any concomitant medications or treatments deemed necessary to provide adequate supportive care due to study protocol. During participation in the clinical trial the patients will be insured as defined by legal requirements.

The investigator will ensure that this study is conducted in full conformance with the principles of the "Declaration of Helsinki" and with the laws and regulations of Austria. The principal investigator of the clinical trial shall guarantee that only appropriately trained personnel will be involved in the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 December 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 1
Worldwide total number of subjects	1
EEA total number of subjects	1

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0

Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	1
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment was prematurely stopped due to patient / protocol incompliance

Pre-assignment

Screening details: -

Period 1

Period 1 title	Baseline (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

not applicable

Arms

Arm title	two arms

Arm description:

Arm A: Ferrinject
Arm B: Aranesp

Arm type	Active comparator
Investigational medicinal product name	Ferinject
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for infusion, Solution for injection
Routes of administration	Intravenous use, Intravenous use

Dosage and administration details:

Dosage: 50 mg/ml

Investigational medicinal product name	Aranesp
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dosage: 500mµg

Number of subjects in period 1	two arms
Started	1
Completed	1

Baseline characteristics

Reporting groups

Reporting group title	Baseline

Reporting group description: -

Reporting group values	Baseline	Total	
Number of subjects	1	1	
Age categorical			
Female (18-64 years)			
Units: Subjects			
Adults (18-64 years)	1	1	
Gender categorical Units: Subjects			
Female	1	1	
Male	0	0	

Subject analysis sets

Subject analysis set title	HB level
Subject analysis set type	Per protocol

Subject analysis set description:

Hb levels will be monitored weekly from study drug administration until Hb normalization (Hb ≥ 11g/dl), an Hb increase of ≥2g/dl or until the maximum of 6 weeks after chemotherapy administration, whichever comes first. The subjects do the laboratory examination (Hb, Hct, RBC count, WBC count with differential, reticulocytes, platelet count) in their local laboratory and the laboratory send the values within 24 hours per fax to the study site. These values will be recorded in the CRF. At the time after the Hb level has normalized (Hb ≥11g/dl) or Hb has increased ≥2g/dl or the maximum of 6 weeks after study drug administration has occurred, the subject will be informed by the site to attend the hospital
once again.

Reporting group values	HB level		
Number of subjects	1		
Age categorical			
Female (18-64 years)			
Units: Subjects			
Adults (18-64 years)	1		
Gender categorical Units: Subjects			
Female	1		
Male	0		

End points

End points reporting groups

Reporting group title	two arms
Reporting group description:	
Arm A: Ferrinject Arm B: Aranesp	
Subject analysis set title	HB level
Subject analysis set type	Per protocol
Subject analysis set description:	
Hb levels will be monitored weekly from study drug administration until Hb normalization (Hb ≥ 11g/dl), an Hb increase of ≥2g/dl or until the maximum of 6 weeks after chemotherapy administration, whichever comes first. The subjects do the laboratory examination (Hb, Hct, RBC count, WBC count with differential, reticulocytes, platelet count) in their local laboratory and the laboratory send the values within 24 hours per fax to the study site. These values will be recorded in the CRF. At the time after the Hb level has normalized (Hb ≥11g/dl) or Hb has increased ≥2g/dl or the maximum of 6 weeks after study drug administration has occurred, the subject will be informed by the site to attend the hospital once again.	

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Assessment type	

Dictionary used

Dictionary name	CTCAE
Dictionary version	4.0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported