Evaluation of the Correlation between fatigue and quality of life in patients with solid tumour, malignant lymphoma or multiple myeloma and treated with Binocrit® for a chemotherapy-induced anaemia (CIROCO)

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Study Ongoing

Administrative details

EU PAS number

EUPAS11057

Study ID

23646

DARWIN EU® study

No

Study countries

☐ France

Study description

CIROCO study is a national, multicenter, prospective, observational study.
Anemia is a biological symptom frequently observed in cancer patients. While the latter maybe related to the cancer disease itself, it is most commonly the consequence of cancer-specific treatments, notably chemotherapy.
Anemia is defined as a reduction in the total amount of circulating functional hemoglobin.
Fatigue is the quality of life(QL)-impacting symptom which is the most commonly reported by patients with cancer undergoing chemotherapy, with an incidence of over 70 % of patients
1. Patients describe it as the symptom which most affects their daily life (67%), or even as their main problem (37%)
2.The EORTC QLQ C30 multicriteria scale 2 has been validated on over 10,000 patients and is widely used in clinical practice to evaluate the QL of cancer patients. The use of a single-criterion evaluation test such as the Fatigue Visual Analog Scale (VAS) which evaluates fatigue on a scale from 0 (no fatigue at all) to 10 (extreme fatigue), is considered, due to its simplicity, as the most appropriate way to self evaluate
3.Binocrit® (epoetin alfa), an erythropoeisis-stimulating agent, is administered to patients with chemotherapy-induced anaemia (CIA) with the aim of increasing their haemoglobin level, avoiding blood transfusions, and improving patient QL 4, notably by improving fatigue. The main objective of the study is to determine the correlation between fatigue, evaluated by VAS, and QL, using EORTC QLQ C30, perceived by patients with solid tumor, malignant lymphoma or multiple myeloma and treated with Binocrit® for a CIA. This study will also help to assess the perception that physicians have of their patients' fatigue. The patient's inclusion and follow-up in the study will occur as part of their usual care. No further tests are planned which could hinder the patients' usual

treatment. All data collected will be anonymized.

Study status

Ongoing

Research institutions and networks

Institutions

Sandoz

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Institution

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 02/03/2015

Actual: 02/03/2015

Study start date
Planned: 24/09/2015

Actual: 26/09/2015

Date of final study report
Planned: 31/08/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

SANDOZ

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

The main objective of the study is to determine the correlation between fatigue,measured using a Visual Analog Scale (VAS), and Quality of Life, evaluated using the EORTC QLQ C30 questionnaire, perceived by patients undergoing chemotherapy for a solid tumour,malignant lymphoma, multiple myeloma presenting with a chemotherapy-induced anaemia and receiving Binocrit®.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

BINOCRIT

Study drug International non-proprietary name (INN) or common name

EPOETIN ALFA

Anatomical Therapeutic Chemical (ATC) code

(B03XA01) erythropoietin

erythropoietin

Medical condition to be studied

Anaemia

Fatigue

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

965

Study design details

Outcomes

The evaluation of the correlation at T0 (inclusion), T1 (follow-up) and T2 (end of follow-up), between the fatigue perceived by the patient and measured using a VAS and the QL score from the EORTC QLQ-C30 questionnaire. *Correlation coefficient between:

-the change in fatigue and the change in QL between T0 and T1 and between T0 and T2 -haemoglobin and the QL -haemoglobin and VAS perceived by patient

*Patient's VAS fatigue perceived by the physician

*Concordance between the VAS (patient and physician)

*Procedure for using Binocrit® based on haemoglobin

*Factors associated with improved fatigue and QL

Data analysis plan

Statistical tests will be bilateral and a significance threshold of 5% will be used.
The raw correlation between the two quantitative variables, fatigue value estimated value and QL score, will be calculated using the Pearson correlation coefficient and will be presented alongside its 95% CI.
If the distributions do not follow a normal distribution or if outliers are observed, the use of the Spearman correlation coefficient will be preferred.
The null hypotheses H0 r=0, r=0.10 and r=0.3 will be tested at a risk level of α = 0.05 in a bilateral situation in order to test respectively if the correlation level is zero, weak or moderate.
The differences observed between the three evaluation timepoints (T0, T1 and T2) will be discussed.
Unless otherwise specified (i.e. calculation of sub-scores in the QL questionnaire, multivariate analyses to look for predictive factors of fatigue and QL improvement), missing data will not be replaced.

Documents

Study publications

Glaus A. Assessment of fatigue in cancer and non-cancer patients and in healthy…

Chouaid C, Colin P, Maloisel F, Mitry E, Zelek l, Le Calvé P. "Regards croisés …

Aaronson NK, Ahmedzai S, Bergman B, et al. The European Organization for Resear...

Aapro MS, Link H. September 2007 update on EORTC guidelines and anemia manageme...

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No