

Efficacy and safety of XM22 compared to pegfilgrastim in patients with breast cancer receiving chemotherapy

Submission date 22/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/01/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Peter Bias

Contact details
Merckle GmbH
A Member of the ratiopharm Group
Clinical Research
Graf-Arco-Straße 3
Ulm
Germany
89075

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
XM22-03

Study information

Scientific Title

Efficacy and safety of XM22 compared to pegfilgrastim in patients with breast cancer receiving chemotherapy. A multinational, multicentre, randomised, double-blind controlled study

Study objectives

Demonstration of non-inferiority of XM22 versus pegfilgrastim in patients with breast cancer during the first cycle of chemotherapy with respect to the duration of severe neutropenia (DSN)

Ethics approval required

Old ethics approval format

Ethics approval(s)

At each study centre, the protocol (dated 29 September 2009) and informed consent form for this study were reviewed and approved by Independent Ethic Committees before inclusion of patients. Amendments to the protocol will be reviewed and approved in the same manner before being implemented.

Study design

Multinational multicentre randomised double blind active controlled phase III study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Breast cancer patients with chemotherapy induced neutropenia

Interventions

XM22: 1 syringe 6 mg per cycle (cycles 1-4)

Pegfilgrastim: 1 syringe 6 mg per cycle (cycles 1-4)

The duration of the study will be 12 weeks. The duration of follow up will be 360 days.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

XM22, pegfilgrastim

Primary outcome measure

Duration of severe neutropenia in cycle 1, defined as grade 4 neutropenia with an ANC $<0.5 \times 10^9/L$

Secondary outcome measures

1. Incidence of febrile neutropenia (FN) by cycle and across all cycles (FN defined as body temperature of $>38.5^\circ C$ for at least one hour, measured orally with a certified standard device, and ANC $<0.5 \times 10^9/L$, including cases of neutropenic sepsis or neutropenic serious or life-threatening infection)
2. Time in hospital and time in intensive care unit due to FN or connected infections
3. Incidence of treatment with i.v. antibiotics due to FN or connected infections
4. DSN in cycles 2, 3, and 4
5. Incidence of severe neutropenia, defined as grade 4 neutropenia with an ANC $<0.5 \times 10^9/L$ in cycles 1, 2, 3 and 4
6. Duration and incidence of very severe neutropenia, defined as ANC $<0.1 \times 10^9/L$ in cycles 1, 2, 3 and 4
7. Depth of ANC nadir in cycles 1, 2, 3, and 4
8. Time to ANC nadir in cycles 1, 2, 3, and 4
9. Time to ANC recovery in cycles 1, 2, 3, and 4
10. Percentage of actually delivered vs. scheduled cumulative chemotherapy dose
11. Proportion of patients with chemotherapy doses reduced, omitted, or delayed
12. Number of days of delay of chemotherapy
13. Overall quality of life as measured by the EORTC QLQ-C30 (version 3) and the EORTC QLQ-BR23

Overall study start date

01/05/2010

Completion date

01/03/2012

Eligibility

Key inclusion criteria

1. Provide signed and dated written informed consent
2. Men and women aged ≥ 18 years
3. The patient must be able to understand and follow instructions and must be able to participate in the study for the entire period
4. Breast cancer high risk stage II, III or IV according to American Joint Committee on Cancer (AJCC) classification
5. Patients planned and eligible to receive 4 cycles of treatment with docetaxel/doxorubicin as routine chemotherapy for their breast cancer disease
6. Chemotherapy naïve
7. Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2
8. Absolute Neutrophil Count (ANC) $\geq 1.5 \times 10^9/L$

9. Platelet count $\geq 100 \times 10^9/L$

10. Adequate cardiac function (including left ventricular ejection fraction $\geq 50\%$ as assessed by echocardiography or equivalent method within 4 weeks prior to randomisation)

11. Adequate hepatic function, i.e. ALT and AST $< 2.5 \times \text{ULN}$, alkaline phosphatase $< 5 \times \text{ULN}$, bilirubin $< \text{ULN}$

12. Adequate renal function, i.e. creatinine $< 1.5 \times \text{ULN}$

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200 (100 per treatment group)

Key exclusion criteria

1. Participation in a clinical trial within 30 days before randomisation.

2. Previous exposure to filgrastim, pegfilgrastim or lenograstim or other G-CSFs in clinical development less than 6 months before randomisation.

3. Known hypersensitivity to docetaxel or doxorubicin, filgrastim, pegfilgrastim or lenograstim.

4. Underlying neuropathy of grade 2 or higher.

5. Treatment with systemically active antibiotics within 72 hours before chemotherapy.

6. Treatment with lithium at inclusion or planned during the entire study.

7. Chronic use of oral corticosteroids.

8. Prior radiation therapy or tumour surgery within 4 weeks before randomisation.

9. Prior bone marrow or stem cell transplantation.

10. Prior malignancy within the previous 5 years other than basal cell or squamous cell carcinomas or in situ carcinoma of the cervix.

11. Any illness or condition that in the opinion of the investigator may affect the safety of the patient or the evaluation of any study endpoint.

12. Pregnant or nursing women. Women of child-bearing potential who do not agree to use a highly effective method of birth control during the entire duration of the study. Highly effective methods of birth control are defined as those which result in a low failure rate (i.e. less than 1% per year) when used consistently and correctly such as implants, injectables, combined oral contraceptives, hormonal IUDs, sexual abstinence or vasectomised partner. Female patients will be considered to be of child-bearing potential unless surgically sterilised by hysterectomy or bilateral tubal ligation, or post-menopausal for at least two years (Postmenopausal is defined as the time after which a woman has experienced twelve consecutive months of amenorrhea without a period).

Date of first enrolment

01/05/2010

Date of final enrolment

01/03/2012

Locations

Countries of recruitment

Bulgaria

Germany

Russian Federation

Ukraine

Study participating centre

Merckle GmbH

Ulm

Germany

89075

Sponsor information

Organisation

BioGeneriX AG (Germany)

Sponsor details

High-Tech-Park Neckarau

Janderstraße 3

Mannheim

Germany

68199

Sponsor type

Industry

Website

<http://www.biogenerix.com>

ROR

<https://ror.org/03xa4xh46>

Funder(s)

Funder type

Industry

Funder Name

BioGeneriX AG (Germany)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/08/2013		Yes	No