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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/06/2010	**Overall study status** Completed	
Last Edited 16/01/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Duration of severe neutropenia in cycle 1, defined as grade 4 neutropenia with an ANC <0.5 x 10*9/L

Key secondary outcome(s))
1. Incidence of febrile neutropenia (FN) by cycle and across all cycles (FN defined as body temperature of >38.5°C for at least one hour, measured orally with a certified standard device, and ANC <0.5 x 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 x 10*9/L in cycles 1, 2, 3 and 4
6. Duration and incidence of very severe neutropenia, defined as ANC <0.1 x 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

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) ≥1.5 x 10*9/L
9. Platelet count ≥100 x 10*9/L
10. Adequate cardiac function (including left ventricular ejection fraction ≥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 x ULN, alkaline phosphatase <5 x ULN, bilirubin <ULN
12. Adequate renal function, i.e. creatinine <1.5 x ULN

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

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)

ROR
https://ror.org/03xa4xh46

Funder(s)

Funder type
Industry

Funder Name
BioGeneriX AG (Germany)

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes