

Efficacy and safety of XM02 compared to filgrastim in patients with breast cancer receiving chemotherapy: A multinational, multicentre, randomised, controlled study

Submission date 21/05/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/05/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/08/2011	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

XM02 is superior to placebo and equivalent to filgrastim on the duration of severe neutropenia in cycle 1.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Romania: National Ethics Committee of Medicamentului Student Clinic (Comisia Nationala de Etica pentru Studiul Clinic al Medicamentului), Av. Sanatescu Str. No 48, Sect. 1, Bucharest, Date of approval: 19/05/2004 (No 1165)

Hungary: Ethics Committee for Clinical Pharmacology, Medical Research Council, Arany J.u. 6-8, H-1051 Budapest. Date of approval: 16/06/2004 (ref: 22972-1/2004-1017EKL)

Lithuania: Lietuvos Bioethics Committee (Lietuvos Bioetikos Komitetas), Kodas 8871059, Vilniaus g. 33-230, LT-2001. Date of approval: 01/06/2004 (ref: 2004-06-02 Nr. 19/3)

Russia: Ethics Committee at the Federal Body of Quality, Efficacy and Safety Control of Medicinal Remedies, 8, Petrovsky Bulvar, Building 1, 103051 Moscow. Date of approval: 16/06/2004 (ref: 2573)

Slovenia: Committee of the Republic of Slovenia for Medical Ethics. Date of approval: 22/06/2004 (ref: 55/06/04)

South Africa: Ethics Committee of the University of the Free State, Kellner Street, Bloemfontein 9301. Date of approval: 16/02/2005 (ref: No ETOVS Nr. 71/04)

Belarus, Chile, Poland: Centres received ethics approval before recruiting participants.

Study design

Multinational, multicentre, randomised, controlled study with parallel groups.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Breast cancer treated by myelotoxic chemotherapy

Interventions

Arm 1: XM02, 5 µg/kg body weight/day subcutaneously (s.c.)

Arm 2: Filgrastim, 5 µg/kg body weight/day s.c.

Arm 3: Placebo, 5 µg/kg body weight/day s.c.

The study drug/placebo was administered in each cycle of chemotherapy daily from day 2 (24 hours after chemotherapy) to maximum day 15, minimum 5 days. Study drug was stopped as soon as ANC $>10 \times 10^9/L$ was reached.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

filgrastim

Primary outcome measure

Duration of severe neutropenia in cycle 1

Secondary outcome measures

1. Secondary efficacy endpoints:

1.1. Incidence of observed febrile neutropenia (FN) (observed FN defined as body temperature of $>38.5^{\circ}C$ for more than 1 hour, measured axillary with a calibrated standard device, and ANC $<0.5 \times 10^9/L$, both measured on the same day) and of protocol defined FN (intake of systemic antibiotics) by cycle and across all cycles

1.2. Duration of severe neutropenia in cycles 2 to 4

1.3. Depth of ANC nadir in cycles 1 to 4

1.4. Times to ANC recovery in cycles 1 to 4

1.5. Mortality

2. Safety endpoints, determined at the beginning and at the end of each chemotherapy cycle until day 85, antibody determination until day 180:

2.1. Adverse events (AEs)

2.3. Safety laboratory assessment

2.4. Physical examination

2.5. Injection site reactions

2.6. Vital signs

2.7. Eastern Cooperative Oncology Group (ECOG) performance

2.8. Immunogenicity (development of antibodies against study drug)

Other:

3. Pharmacokinetics in a subset of patients

Overall study start date

30/12/2004

Completion date

Eligibility

Key inclusion criteria

1. Signed and dated written informed consent
2. Age above or equal 18 years, both males and females
3. Breast cancer high risk stage II, or stage III or IV (classification according to American Joint Committee on Cancer [AJCC])
4. Patients planned/eligible to receive treatment with docetaxel/doxorubicin as routine chemotherapy (CTX) for their breast cancer disease
5. CTX naïve
6. Eastern Cooperative Oncology Group (ECOG) performance status below or equal 2
7. Absolute neutrophil count (ANC) above or equal $1.5 \times 10^9/L$
8. Platelet count above or equal $100 \times 10^9/L$
9. Adequate cardiac function (including left ventricular ejection fraction above or equal 50% as assessed by echocardiography within 4 weeks prior to randomisation)
10. Adequate hepatic function i.e., alanine and aspartate aminotransferases (ALT/AST) $<2.5 \times$ upper limit of normal (ULN), alkaline phosphatase (AP) $<5 \times$ ULN, bilirubin $<ULN$
11. Adequate renal function, i.e., creatinine $<1.5 \times$ ULN

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

350

Key exclusion criteria

1. Participation in a clinical trial within 30 days before randomisation
2. Previous exposure to filgrastim, pegfilgrastim or lenograstim
3. Known hypersensitivity to docetaxel
4. Underlying neuropathy of grade 2 or higher
5. Treatment with systemically active antibiotics within 72 hours before CTX
6. Treatment with lithium
7. Chronic use of oral corticosteroids
8. Prior radiation therapy 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 could affect the safety of the

patient or the evaluation of any study endpoint

12. Pregnant or nursing women were excluded. Women of child-bearing potential had to agree to use a chemical or barrier contraceptive during the treatment period.

Date of first enrolment

30/12/2004

Date of final enrolment

26/09/2005

Locations

Countries of recruitment

Belarus

Brazil

Chile

Hungary

Lithuania

Poland

Romania

Russian Federation

Slovenia

South Africa

Study participating centre

Faculdade de Medicina do ABC

Santo André

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Sponsor information

Organisation

BioGeneriX AG (Germany)

Sponsor details

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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