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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

Registration date
29/05/2008

Overall study status
Completed

Last Edited
16/08/2011

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

XM02-02-INT

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 x 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°C for more than 1 hour, measured axillary with a calibrated standard device, and ANC <0.5 x 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

26/09/2005

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 x 10^9/L
8. Platelet count above or equal 100 x 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 x upper limit of normal (ULN), alkaline phosphatase (AP) <5 x ULN, bilirubin <ULN
11. Adequate renal function, i.e., creatinine <1.5 x 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
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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