ISRCTN56891934 https://doi.org/10.1186/ISRCTN56891934

Dose-finding of a fixed dose XM22 in patients with breast cancer receiving 4 cycles of chemotherapy versus 6 mg Neulasta®

Submission date
29/04/2008

Recruitment status
No longer recruiting

Registration date
22/05/2008

Overall study status
Completed

Last Edited
30/08/2011

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
XM22-02-INT

Study information

Scientific Title

Study objectives
The primary objective of this study is dose-finding of a fixed dose of XM22.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Multi-Centric Clinical Trials of the University Hospital Motol, V uvalu 84, 150 06 Praha 5, Czech Republic. Date of approval: 09/04/2008 (ref: EK-279/08)

Study design
Multinational, multicentre, randomised, double-blind, controlled 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Participants will be randomly allocated to the following two arms:
1. Neulasta®, 6 mg, administered subcutaneously once per chemotherapy cycle
2. XM22 administered subcutaneously once per chemotherapy cycle

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Neulasta®, XM22

Primary outcome measure
Duration of severe neutropenia (DSN) in cycle 1

Secondary outcome measures
Incidence of febrile neutropenia (FN) in cycles 1, 2, 3 and 4

Overall study start date
30/04/2008

Completion date
28/02/2009

Eligibility

Key inclusion criteria
1. Men and women aged >= 18 years
2. Signed and dated written informed consent
3. Breast cancer high risk stage II, or stage III or IV
4. Patients planned/eligible to receive treatment with docetaxel/doxorubicin as routine chemotherapy for their breast cancer disease
5. Chemotherapy-naïve
6. Eastern Cooperative Oncology Group (ECOG) performance status <= 2
7. ANC >= 1.5 x 10^9/L
8. Platelet count >= 100 x 10^9/L
9. Adequate cardiac function (including left ventricular ejection fraction >= 50% as assessed by echocardiography or equivalent method within 4 weeks prior to randomisation)
10. Adequate hepatic function, i.e., alanine aminotransferase (ALT)/aspartate transaminase (AST) <2.5 x upper limit of normal (ULN), alkaline phosphatase <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
200

Key exclusion criteria
1. Participation in a clinical trial within 30 days before randomisation
2. Previous exposure to filgrastim, pegfilgrastim, lenograstim, or other granulocyte-colony stimulating factors (G-CSFs) in clinical development
3. Known hypersensitivity to docetaxel

4. Underlying neuropathy of grade 2 or higher
5. Treatment with systemically active antibiotics within 72 hours before chemotherapy
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 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 childbearing potential unless surgically sterilised by hysterectomy or bilateral tubal ligation, or post-menopausal for at least two years.

Date of first enrolment
30/04/2008

Date of final enrolment
28/02/2009

Locations

Countries of recruitment
Czech Republic

Germany

Hungary

Poland

Romania

Russian Federation

Ukraine

Study participating centre
Universitäts-Frauenklinik
Frankfurt
Germany
60596

Sponsor information

Organisation
BioGeneriX AG (Germany)

Sponsor details
Janderstrasse 3
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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