

Efficacy and safety of XM22 in patients with non small cell lung cancer receiving cisplatin / etoposide chemotherapy

Submission date 22/04/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/06/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 16/01/2019	Condition category Cancer	☐ Individual participant data

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
XM22-04

Study information

Scientific Title

Efficacy and safety of XM22 in patients with non small cell lung cancer receiving cisplatin / etoposide chemotherapy. A multinational, multicentre, randomised, double-blind placebo-controlled study

Study objectives

Demonstration of superiority of XM22 versus placebo when administered for up to a maximum of four cycles chemotherapy (CTX) in patients with non small cell lung cancer (NSCLC)

Ethics approval required

Old ethics approval format

Ethics approval(s)

At each study centre, the protocol (dated 01/10/2009) 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

Primary study design

Interventional

Study design

Multinational multicentre randomised double blind placebo controlled phase III study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

NSCLC patients with chemotherapy induced neutropenia

Interventions

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

Placebo: 1 syringe 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

Primary outcome(s)

Incidence of febrile neutropenia (FN) in the first cycle of chemotherapy

Key secondary outcome(s)

1. Incidence of febrile neutropenia in cycles 2, 3 and 4 and across all cycles
2. Duration and 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

3. Duration and incidence of very severe neutropenia, defined as ANC $<0.1 \times 10^9/L$ in cycles 1, 2, 3 and 4
4. Depth of ANC nadir in all cycles
5. Time to ANC nadir in cycles 1, 2, 3 and 4
6. Time to ANC recovery in all cycles
7. Percentage of actually delivered vs. scheduled cumulative chemotherapy dose
8. Proportion of patients with chemotherapy doses reduced, omitted, or delayed
9. Number of days of delay of chemotherapy
10. Overall quality of life as measured by the EORTC QLQ-C30 (version 3) and the EORTC QLQ-LC13
11. Time in hospital and time in intensive care unit due to febrile neutropenia or connected infections
12. Incidence of treatment with i.v. antibiotics due to FN or connected infections
13. Incidence of patients requiring prophylactic open treatment

Completion date

01/03/2012

Eligibility

Key inclusion criteria

1. Provide signed and dated written informed consent
2. Men and women aged ≥ 18
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. Patients with NSCLC stage IIIB/IV, histologically or cytologically documented
5. Patients planned and eligible to receive 4 cycles of the predefined cisplatin / etoposide-based, myelosuppressive CTX
6. Life-expectancy of at least 4 months
7. CTX naïve
8. Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2
9. Absolute Neutrophil Count (ANC) $\geq 1.5 \times 10^9/L$
10. Platelet count $\geq 100 \times 10^9/L$
11. Adequate hepatic function, i.e. ALT and AST $<2.5 \times ULN$, alkaline phosphatase $<5 \times ULN$, bilirubin $<ULN$
12. Adequate renal function, i.e. creatinine $<1.5 \times ULN$
13. Adequate hepatic, cardiac, bone marrow and renal function for the chosen CTX regimen

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 filgrastim, pegfilgrastim, lenograstim, cisplatin or etoposide.
4. Patient planned for non-myelosuppressive CTX.
5. Patients with an individual high risk for febrile neutropenia in respect of the cisplatin /etoposide CTX according to the assessment of the investigator. Risk factors are age >65 years, low performance status, poor nutritional status, and liver, renal or cardiovascular disease.
6. Patient meeting any contraindication for the chosen CTX regimen.
7. Treatment with systemically active antibiotics within 72 hours before CTX.
8. Treatment with lithium at inclusion or planned during the entire study.
9. Patient to be treated with combined chemo-/ radiotherapy during the foreseen participation in this study.
10. Chronic use of oral corticosteroids (except low dose chronic treatment with ≤ 20 mg/day prednisolone or equivalent dose for chronic obstructive pulmonary disease).
11. Prior radiation therapy or tumour surgery within 4 weeks before randomisation.
12. Prior bone marrow or stem cell transplantation.
13. Prior malignancy within the preceding 5 years other than non-melanoma skin cancer or in situ cervical carcinoma.
14. 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.
15. 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

Belarus

Bosnia and Herzegovina

Bulgaria

Germany

Poland

Romania

Russian Federation

Serbia

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	03/07/2015	16/01/2019	Yes	No
Results article	results	01/12/2016	16/01/2019	Yes	No