A Global, Phase 3, Randomized, Multicenter, Open-Label Study to Investigate the Efficacy and Safety of Furmonertinib Compared to Platinum-Based Chemotherapy as First-Line Treatment for Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer with Epidermal Growth Factor Receptor Exon 20 Insertion Mutations

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This study has been transitioned to CTIS with ID 2022-502977-41-00 check the CTIS register for the current data. Primary ObjectiveTo assess the efficacy of furmonertinib compared to platinum-based chemotherapy using progression-free survival (PFS)...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53471

Source
ToetsingOnline

Brief title
A study of Furmonertinib in Patients With NSCLC (FURMO-004)

Condition

- Other condition
- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

Synonym
Lung cancer, patients with advanced or metastatic non-small cell lung cancer (NSCLC)

Health condition

Non-squamous nonsmall cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: ArriVent BioPharma, Inc.
Source(s) of monetary or material Support: Industry

Intervention

Keyword: Furmonertinib, NSCLC, open-Label, Phase III

Outcome measures

Primary outcome

PFS, where PFS is defined as the time from randomization to the first

occurrence of disease progression, as determined by blinded independent central

review (BICR) using Response Evaluation Criteria in Solid Tumors, version 1.1

(RECIST v1.1), or death from any cause, whichever occurs first

Secondary outcome

OS, defined as the time from randomization to death from any cause

• PFS as determined by investigator assessment using RECIST v1.1

• Objective response rate (ORR), defined as the percentage of patients with a

complete response (CR) or partial response (PR) relative to the total number of

patients by BICR and investigator assessment using RECIST v1.1

• Duration of response (DOR), defined as the time from first documented evidence of CR or PR until the first documented evidence of disease progression or death, whichever occurs earlier, as determined by BICR and investigator assessment using RECIST v1.1

Furmonertinib*ArriVent BioPharma, Inc.

16/Protocol FURMO-004 Version 2.0

• Time to second progression (PFS2), defined as the time from randomization to second progression, (i.e., earliest of the subsequent progression events after initiation of new anticancer treatment), or death from any cause, whichever occurs first. PFS2 is evaluated per local standard practice by investigator.

• PFS by BICR and investigator assessment using RECIST v1.1 in patients with a history or presence of brain metastases at baseline

• Time to central nervous system (CNS) metastases by BICR and investigator assessment using RECIST v1.1

* Time to CNS metastases is defined as the time from the date of randomization until the date of newly diagnosed CNS lesions by RECIST v1.1.

• CNS ORR, evaluated by BICR per modified RECIST criteria in patients with CNS lesion(s) on baseline brain scan

• CNS DOR, evaluated by BICR per modified RECIST criteria in patients with CNS lesion(s) on baseline brain scan

• CNS PFS, evaluated by BICR per modified RECIST criteria in patients with CNS lesion(s) on baseline brain scan

* CNS PFS is defined as the time from randomization to the first occurrence of

CNS progression according to modified RECIST by BICR, or death from any cause, whichever comes first.

Change from baseline in European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30)

• Change from baseline in EORTC QLQ Lung Cancer Module Core 13 (QLQ-LC13)

• Change from baseline in Non-Small Cell Lung Cancer Symptom Assessment Questionnaire (NSCLC-SAQ)

• Time to deterioration of lung-related symptoms of dyspnea, cough, and chest pain

• Incidence and severity of adverse events (AEs), with severity determined according to National Cancer Institute Common Terminology Criteria for Adverse Events, version 5.0 (NCI CTCAE v5.0)

• Change from baseline in safety-related clinical laboratory test results

• Plasma concentrations of furmonertinib and its major metabolite (AST5902) at specified time points collected from patients receiving furmonertinib

Study description

Background summary

In laboratory studies the study drug has been shown to shrink or slow the growth of several different types of cancers or tumors in animals whose tumor cells have a change in the EGFR or HER2 gene. This change in the EGFR or HER2 gene can cause cells to grow abnormally and develop into cancer. It is hoped that the study drug will stop the abnormal EGFR or HER2 gene from causing cells to grow abnormally.
The study drug is experimental, which means that health authorities have not approved the study drug for the treatment of this type of NSCLC. Doctors are not allowed to prescribe or use this study drug outside research.
Chemotherapy used in this study is approved for treatment of NSCLC and is

commonly used in treating patients who have a change in a gene called epidermal growth factor receptor (EGFR).

Study objective

This study has been transitioned to CTIS with ID 2022-502977-41-00 check the CTIS register for the current data.

Primary Objective
To assess the efficacy of furmonertinib compared to platinum-based chemotherapy using progression-free survival (PFS) in previously untreated patients with locally advanced or metastatic non-squamous NSCLC with EGFR exon 20 insertion mutations.
Secondary Objectives
To assess the efficacy of furmonertinib compared to platinum-based chemotherapy using overall survival (OS), tumor response, and progression in previously untreated patients with locally advanced or metastatic non-squamous NSCLC with EGFR exon 20 insertion mutations.
To assess the impact of furmonertinib compared to platinum-based chemotherapy on patients* disease-related symptoms and health-related quality of life.
To evaluate the safety and tolerability of furmonertinib compared to platinum-based chemotherapy in patients with previously untreated locally advanced or metastatic non-squamous NSCLC with EGFR exon 20 insertion mutations.
To characterize the pharmacokinetics (PK) of furmonertinib and its major metabolite (AST5902).
Exploratory Objectives
To assess the efficacy of furmonertinib compared to platinum-based chemotherapy in patients with previously untreated, locally advanced or metastatic non-squamous NSCLC with EGFR exon 20 insertion mutations as measured by central tumor tissue and/or blood-based assay for EGFR exon 20 insertion mutations.
To assess the impact of furmonertinib compared to platinum-based chemotherapy on patients* disease-related symptoms and health-related quality of life.
To compare the change in tumor tissue gene mutation profile from baseline to during treatment and at disease progression, and the consistency and change of mutation profile in tumor tissue and circulating tumor DNA (ctDNA) in the peripheral blood.
To compare the change in gene mutation profile from baseline to during treatment and at disease progression based on the ctDNA in the peripheral blood.
To explore the relationship between exploratory biomarkers in blood, plasma, and tumor tissue and safety, efficacy, or other biomarker endpoints.
To explore the relationship between PK and endpoints that may include but are not limited to efficacy, safety, and patient-reported outcomes (PROs), where deemed appropriate

Study design

This is a global, Phase 3, randomized, multicenter, open-label study evaluating the efficacy and safety of furmonertinib at 2 dose levels (160 mg and 240 mg) compared to platinum-based chemotherapy in previously untreated patients with locally advanced or metastatic non-squamous NSCLC with EGFR exon 20 insertion mutations.
A target of approximately 375 patients will be randomized in a 1:1:1 ratio to treatment with furmonertinib 240 mg QD, furmonertinib 160 mg QD, or platinum-based chemotherapy. Randomization will be stratified by history or presence of CNS metastases at baseline (Yes vs No), region (Asia Pacific vs Non-Asia Pacific), and sex at birth (Male vs Female). History or presence of CNS metastases at baseline is defined as any history of CNS metastases or any evidence of CNS metastases from tumor scan prior to randomization.
The study is divided into 3 periods: Screening, Treatment, and Long-Term Survival Follow-Up. Individual patient participation in the Screening Period will be up to 28 days. During the Treatment Period, study drug will be administered in 21-day cycles. Patients assigned to furmonertinib will take the assigned dose daily. Patients assigned to chemotherapy will receive platinum-based chemotherapy (carboplatin or cisplatin based on investigator*s choice) + pemetrexed intravenously (IV) on Day 1 of each 21-day cycle for 4 cycles, followed by maintenance therapy with pemetrexed as per local standard of care. Patients will continue to receive treatment until unacceptable toxicity, loss of clinical benefit, radiographic objective disease progression by the investigator or confirmed progression by BICR, death, or start of new anticancer therapy not specified in this protocol. During the Long-Term Survival Follow-Up Period, information on survival follow-up, new anticancer therapy, and disease progression assessment post the new anticancer therapy will be collected via telephone calls, emails, patient medical records, and/or clinic visits approximately every 6 weeks until PFS2 is reached, then subsequently every 3 months until death, loss to follow-up, withdrawal of consent, or study discontinuation by the Sponsor. Patients will remain in the Long-Term Survival Follow-Up Period until death, loss to follow-up, withdrawal of consent, or study discontinuation. The study will continue until last patient, last visit, which is expected to be approximately 3 years after the last patient is randomized. The anticipated total study duration is approximately 5 years from the first randomized patient.
Crossover from the control arm (platinum-based chemotherapy) to the experimental arm(s) (furmonertinib) will be permitted following confirmed disease progression as assessed by central review and if the patient meets crossover eligibility criteria outlined in the protocol.
BICR will be performed using RECIST v1.1 and modified RECIST to assess radiographic disease progression and responses for PFS, ORR, DOR, CNS ORR, CNS DOR, and CNS PFS as appropriate.
An independent data monitoring committee (iDMC) will evaluate and monitor safety and efficacy data during the study.

Intervention

For this study, furmonertinib, pemetrexed, carboplatin, and cisplatin are considered investigational medicinal products (IMPs).
Furmonertinib is manufactured by WuXi SynTheAll Pharmaceutical Co., Ltd. (WuXi STA) and will be supplied as an oral tablet of 40 mg strength.
Doses: 240 mg or 160 mg QD orally (PO)
Patients will be instructed to take tablets by mouth daily on an empty stomach (i.e., food should be avoided for at least 2 hours before and at least 1 hour post dose) at about the same time each day. Each dose should be taken with water. One treatment cycle consists of 3 weeks. Furmonertinib tablets must be protected from light and stored at <= 25°C (<= 77°F).
Pemetrexed, carboplatin, and cisplatin will be used in the commercially available formulation.
Pemetrexed is an intravenous (IV) infusion dosed at 500 mg/m2 on Day 1 of 21-day cycles (every 3 weeks) for 4 cycles, followed by pemetrexed maintenance (500 mg/m2) every 3 weeks. Pemetrexed will be administered with either carboplatin or cisplatin.
Carboplatin will be sourced locally or provided by the Sponsor and will be used in the commercially available formulation. Carboplatin is an IV infusion dosed at area under the concentration-time curve (AUC) of 5 mg•min/mL on Day 1 of 21-day cycles (every 3 weeks) for 4 cycles.
Cisplatin will be sourced locally or provided by the Sponsor and will be used in the commercially available formulation. Cisplatin is an IV infusion administered at 75 mg/m2 on Day 1 of 21-day cycles (every 3 weeks) for 4 cycles.

Study burden and risks

The study contains a screening phase, treatment phase and a follow-up phase. Everyone who takes part in this study will receive study drug(s). A draw will decide which treatment you are given.
If you are randomized to furmonertinib, you will get either 4 or 6 pills of the study drug, furmonertinib (each pill is 40 mg strength)
If you are randomized to the chemotherapy group, you will receive two chemotherapy drugs both given intravenously (in your vein). One is a platinum chemotherapy (either carboplatin or cisplatin). Your doctor will decide which platinum drug is most suitable for you. You will also receive a second chemotherapy drug called pemetrexed. Both drugs will be given intravenously on Day 1 of a 21-day cycle for 4 cycles and then pemetrexed only on Day 1 of cycle 5 and beyond.
During this study, you will be closely evaluated to see how you are doing with the study treatment. Your visits will be approximately every 3 weeks while you are receiving treatment. The first two visits may last up to approximately 9 hours. Subsequent visits will last between 1 and 3 hours
The subject will have to undergo several examinations, tests and/or procedures before, during and after his/her treatment. Please referto the procedure table In the ICF and Schedule of Assessment of the protocol for more information.
In addition, questions are asked about the medical history, demographics and

eligibilty questions
Subjects will also be tested for HIV and hepatitis. Female patients will be tested for pregnancy .
The anticipated total duration of the study will depend on how your lung cancer responds to treatment. This could range from 1 day to up to 60 months.
Possible side effects that are already known are described in the Investigator's Brochure and the patient informed consent form.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

atients must meet the following criteria for study entry:
1. Signed Informed Consent Form
2. Age >= 18 years at time of signing Informed Consent Form

3. Ability to comply with the study protocol, in the investigator*s judgment
4. Measurable disease per RECIST v1.1
Note: Measurable lesion can neither be subject to local therapy such as radiotherapy nor used for biopsy in the Screening Period; if there is only 1 measurable lesion, this lesion will be permitted to be biopsied. However, the baseline radiologic examination should be performed for this lesion at least 14 days after biopsy.
5. Histologically or cytologically documented, locally advanced or metastatic non-squamous NSCLC not amenable to curative surgery or radiotherapy
6. Documented validated results confirming the presence of an EGFR exon 20 insertion mutation (i.e., addition of 1 or more amino acids) in tumor tissue or blood from local or central testing via:
• A validated next-generation sequencing (NGS) assay or a validated polymerase chain reaction (PCR) test with confirmation by Sanger sequencing performed at a Clinical Laboratory Improvement Amendments (CLIA) or equivalently certified laboratory.
* If local testing does not meet the above criteria, then a central test designated by the Sponsor or a commercially available NGS assay should be performed as specified in the laboratory manual.
7. Consent to provide archival tumor tissue specimen (formalin-fixed, paraffin-embedded [FFPE] tissue block [preferred] or at least 15 unstained, serially cut sections on slides from FFPE tumor specimen). The specimens should be provided during screening or no later than within 30 days of Cycle 1, Day 1 and must be accompanied by a pathology report.
• It is preferred that the specimen is prepared from the most recently collected and available tumor tissue. See the laboratory manual for instructions.
8. No prior systemic anticancer therapy regimens received for locally advanced or metastatic NSCLC including prior treatment with any EGFR-targeting agents (e.g., previous EGFR tyrosine kinase inhibitors (EGFR-TKIs), monoclonal antibodies, or bispecific antibodies)
9. Patients who have received prior neo-adjuvant and/or adjuvant chemotherapy, immunotherapy, or chemoradiotherapy for non-metastatic disease must have experienced a treatment-free interval of at least 12 months.
10. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
11. Life expectancy of >= 12 weeks
12. Adequate hematologic and organ function within 14 days prior to initiation of study treatment, defined by the following:
• Absolute neutrophil count >= 1500/µL
• Hemoglobin >= 9 g/dL
• Platelet count >= 100,000/µL
• Total bilirubin <= 1.5 × upper limit of normal (ULN) or <= 3 × ULN in the presence of documented Gilbert*s Syndrome (unconjugated hyperbilirubinemia)
• Aspartate aminotransferase (AST), alanine aminotransferase (ALT), and alkaline phosphatase (AP) <= 2.5 × ULN, with the following exceptions:
* Patients with documented liver metastases may have AST, ALT, and/or AP <= 5.0 × ULN.

* Patients with documented bone metastases may have AP <= 5.0 × ULN.
• Creatinine clearance >= 45 mL/min on the basis of the Cockcroft-Gault estimation:
(140 - age) × (weight in kg) × (0.85 if female)
72 × (serum creatinine in mg/dL)
• International normalized ratio (INR) <= 1.5 × ULN and activated partial thromboplastin time (aPTT) <= 1.5 × ULN
Note: This applies only to patients who are not receiving therapeutic anticoagulation. Patients receiving therapeutic anticoagulation should be on a stable dose for at least 1 week prior to Cycle 1, Day 1.
13. For women of childbearing potential (WOCBP): Agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception, and agreement to refrain from donating eggs, as defined below:
• A woman is considered to be of childbearing potential if she is postmenarchal, has not reached a postmenopausal state >= 12 continuous months of amenorrhea with no identified cause other than menopause, and is not permanently infertile due to surgery (i.e., removal of ovaries, fallopian tubes, and/or uterus) or another cause as determined by the investigator (e.g., Müllerian agenesis). The definition of childbearing potential may be adapted for alignment with local guidelines or regulations.
• WOCBP must remain abstinent or utilize a barrier method such as a condom plus an additional contraceptive method that together result in a failure rate of < 1% per year during the treatment period and at least 6 months after discontinuation of study treatment. WOCBP must refrain from donating eggs during the Treatment Period and 6 months after discontinuation of study treatment.
• Examples of contraceptive methods with a failure rate of < 1% per year include bilateral tubal ligation, male sterilization, hormonal contraceptives that inhibit ovulation, hormone-releasing intrauterine devices, and copper intrauterine devices.
• The reliability of sexual abstinence should be evaluated in relation to the duration of the clinical trial and the preferred and usual lifestyle of the patient.
Periodic abstinence (e.g., calendar, ovulation, symptothermal, or postovulation methods) and withdrawal are not adequate methods of contraception. If required per local guidelines or regulations, locally recognized adequate methods of contraception and information about the reliability of abstinence will be described in the local Informed Consent Form.
• WOCBP (including those who have had a tubal ligation) should not be breastfeeding and must have a negative serum pregnancy test result within 14 days prior to initiation of study drug.
14. For men who are not surgically sterile: Agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception, and agreement to refrain from donating sperm, as defined below:

• With a female partner of childbearing potential who is not pregnant, men must remain abstinent or use a condom plus an additional contraceptive method that together result in a failure rate of < 1% per year during the Treatment Period and
for at least 6 months after discontinuation of study treatment. Patients should refrain from donating sperm from the start of dosing until 6 months after discontinuing study treatment.
• With pregnant female partners, men must remain abstinent or use a condom to avoid exposing the embryo during the Treatment Period and for at least 60 days after discontinuation of study treatment.
• The reliability of sexual abstinence should be evaluated in relation to the duration of the clinical trial and the preferred and usual lifestyle of the patient.
Periodic abstinence (e.g., calendar, ovulation, symptothermal, or postovulation methods) and withdrawal are not adequate methods of contraception. If required per local guidelines or regulations, locally recognized adequate methods of contraception and information about the reliability of abstinence will be described in the local Informed Consent Form.
15. Patients with CNS metastases are eligible, provided they meet all of the following
criteria:
• Measurable disease outside the CNS
• No ongoing requirement for corticosteroids as therapy for CNS metastases, with corticosteroids discontinued for >= 2 weeks prior to enrollment
• No ongoing symptoms attributed to CNS metastases
• No active CNS metastases or spinal cord compression (i.e., progressing or requiring anticonvulsants or corticosteroids for symptomatic control)
• No known or suspected leptomeningeal disease
• Patients with previously treated brain metastases:
* No evidence of interim CNS disease progression between the completion of previous CNS directed therapy and the screening radiographic CNS imaging
* Patients may receive local therapy provided that they

Exclusion criteria

Patients who meet any of the following criteria will be excluded from study entry:
1. Inability or unwillingness to swallow pills
2. Inability to comply with study and follow-up procedures
3. Malabsorption syndrome or other conditions that would interfere with enteral absorption
4. Pleural effusion, pericardial effusion, or ascites requiring recurrent drainage
procedures biweekly or more frequently
• Indwelling pleural or abdominal catheters may be allowed, provided the patient

has adequately recovered from the procedure, is hemodynamically stable, and has symptomatically improved.
5. Severe acute or chronic infections, including:
• Uncontrolled acute infection, active infection that necessitates systemic treatment, or systemic antibiotic treatment within 2 weeks prior to the first dose
of investigational product.
• Patients with uncontrolled human immunodeficiency virus (HIV) infection (defined as CD4+ T cell count < 350 cells/µL).
Note: Patients must have been on established antiretroviral therapy (ART) for at least four weeks and have an HIV viral load < 400 copies/mL prior to enrollment). If the lower limit of detection of HIV viral load assay at the site is
higher than 400 copies/mL or with units other than copies/mL, patients with an HIV viral load result lower than the lower limit of detection in the site are considered eligible. Patients with unknown HIV infection status who do not agree to take HIV test are not eligible.
• Patients with active chronic hepatitis B or with active hepatitis C infection, which includes patients who are hepatitis B surface antigen (HBsAg)-positive or hepatitis C virus (HCV) antibody-positive at screening, are not eligible until further definite quantitative testing of hepatitis B virus (HBV) DNA (e.g., <= 2500
copies/mL or 500 IU/mL) and HCV ribonucleic acid (RNA) tests (e.g., <= lower limit of detection) can conclusively rule out presence of active hepatitis B or C
infection that requires treatment.
Note: If a patient has a negative HBsAg test and a positive total HbcAb test at screening, an HBV DNA test must also be performed to determine if the patient has an HBV infection. Patients who are carriers of HBV, with stable HBV infection (e.g., HBV DNA quantitative test showed DNA <= 2500 copies/mL or 500 IU/mL) after medical treatment or with cured hepatitis C are permitted to enroll. If the lower limit of detection of HBV DNA assay in the site is higher than 2500 cps/mL or 500 IU/mL, patients with HBV DNA quantitative test result lower than the lower limit of detection in the site are considered eligible.
6. In the setting of a pandemic or epidemic, screening for active infections should be
considered according to local or institutional guidelines or those of applicable professional societies (e.g., American Society of Clinical Oncology or European Society for Medical Oncology).
7. Previous interstitial lung disease (ILD), drug-induced ILD, radiation pneumonitis, or active ILD
8. History of or active clinically significant cardiovascular dysfunction, including the following:
• History of stroke or transient ischemic attack within 6 months prior to first dose of study drug
• History of myocardial infarction within 6 months prior to first dose of study drug

• New York Heart Association (NYHA) Class III or IV cardiac disease or congestive heart failure requiring medication
• Uncontrolled arrhythmias, or history of or active ventricular arrhythmia requiring medication
• Coronary heart disease that is symptomatic or unstable angina
9. Mean resting corrected QT interval (QTc) > 470 msec, obtained from triplicate electrocardiograms (ECGs), using the screening clinic ECG machine-derived Fridericia*s formula (QTcF) value
10. Clinically significant prolonged QT interval or other arrhythmia or clinical status considered by investigators that may increase the risk of prolonged QT interval (e.g., complete left bundle branch block, third-degree atrioventricular block, second degree heart block, PR interval > 250 msec, congenital long QT syndrome, family history of long QT syndrome or unexplained sudden death under 40 years of age in first degree relatives, serious hypokalemia, heart failure) or current use of the drugs that may lead to prolonged QT interval
11. Symptomatic hypercalcemia requiring continued use of bisphosphonate therapy or denosumab
12. Significant traumatic injury or major surgical procedure within 4 weeks prior to Day 1 of Cycle 1
13. Patients with chronic diarrhea, short bowel syndrome or significant upper GI surgery including gastric resection, a history of inflammatory bowel disease (e.g., Crohn*s disease or ulcerative colitis), or any active bowel inflammation (including diverticulitis)
14. Any other diseases, pulmonary dysfunction, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of an investigational drug, that may affect the interpretation of the results, or renders the patients at high risk from treatment complications (e.g., uncontrolled hypertension, active bleeding)
15. Radiation therapy (other than palliative radiation to bone metastases and radiation to CNS metastases as described above) as cancer therapy within 4 weeks prior to initiation of study treatment
16. Palliative radiation to bone metastases within 2 weeks prior to initiation of study drug
17. Any unresolved toxicities from prior therapy (e.g., adjuvant chemotherapy) > Grade 1 at initiation of study drug, with the exceptions of alopecia and prior platinum therapy-related Grade 2 neuropathy
18. History of other malignancy within 3 years prior to screening, with the exception of patients with a negligible risk of metastases or death and/or treated with expected curative outcome (such as appropriately treated carcinoma in situ of the cervix, nonmelanoma skin carcinoma, localized prostate cancer, or ductal carcinoma in situ)
19. Pregnant or breastfeeding or intending to become pregnant during the study or within 60 days after the final dose of study drug
20. Use of a strong cytochrome P450 3A4 (CYP3A4) inhibitor within 7 days prior to the first dose of investigational product or a strong CYP3A4 inducer within

21 days prior to the first dose of investigational product
21. Use of an herbal medicine (e.g., Chinese medicine or traditional Chinese medicine preparation indicated for cancer, or a traditional Chinese medicine or traditional Chinese medicine preparation with adjuvant anticancer effects) within 2 weeks prior to the first dose of investigational product or is expected to be used during the study
22. History of allergic reactions to any components, including excipients, of the furmonertinib drug product
23. History of allergic reactions to pemetrexed, cisplatin, carboplatin, other platinum-containing compounds, or other components of their preparation

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-06-2023
Enrollment:	2
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Furmonertinib Mesylate
Generic name:	Furmonertinib

Ethics review

Approved WMO Date:	09-02-2023
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	13-04-2023
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	NCT0560770
EU-CTR	CTIS2022-502977-41-00
EudraCT	EUCTR2022-002006-24-NL
CCMO	NL82942.041.23