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A phase 2, open-label, parallel cohort study of subcutaneous amivantamab in multiple regimens in patients with advanced or metastatic solid tumors including EGFR-mutated non-small cell lung cancer

Submission date
26/08/2022

Recruitment status
No longer recruiting

Registration date
25/11/2022

Overall study status
Ongoing

Last Edited
04/12/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Metastatic NSCLC is an advanced form of cancer that has spread from the lungs to other areas of the body. Amivantamab targets the epidermal growth factor receptor (EGFR) and mesenchymal-epithelial transition factor receptor (MET). Amivantamab as an injection in a vein is being developed in variety of indications for lung cancer. A subcutaneous formulation (injection under the skin) of amivantamab (SC-CF) is being developed to improve patient experience.

This study aims to confirm that amivantamab SC-CF has similar anti-cancer activity similar to what is seen in amivantamab as an injection in a vein in combination regimens.

Who can participate?
This study will include male and female participants 18 years old or above.

What does the study involve?
Participants will be randomly divided into 4 groups as shown below and will receive:
1. Group 1:
- Amivantamab SC-CF 1600 milligrams (mg)/ 2240 mg on Cycle 1 Days 1, 8, 15, and 22 and on Day 1 and 15 of each next 28-day cycle, starting with Cycle 2, and lazertinib 240 mg orally once daily.
2. Group 2:
- Amivantamab SC-CF 2560 mg/ 3360 mg on Cycle 1 Days 1, 8, and 15 and on Day 1 of each next 21-day cycle, starting with Cycle 2, carboplatin 750 mg every 3 weeks (Q3W) up to 4 cycles and pemetrexed 500 milligrams per meter square (mg/m*2) Q3W.
3. Group 3
- Amivantamab SC-CF 2560 mg/ 3360 mg on Cycle 1 Days 1, 8, and 15 and on Cycle 1 Days 1, 8, and 15 and on Day 1 of each next 21-day cycle, starting with Cycle 2, lazertinib 240 mg orally once daily, carboplatin 750 mg Q3W up to 4 cycles and pemetrexed 500 mg/m*2 Q3W.

4. Group 4:
- Amivantamab SC-CF 1600 mg/ 2240 mg in each cycle 28-day cycle, lazertinib 240 mg orally once daily (where applicable).
5. Group 5:
-Amivantamab SC-CF 1600 mg/2240 mg (if BW ≥80 kg) on Cycle 1 Days 1, 8, 15, and 22, followed by 3200 mg/4320 mg (if BW ≥80 kg) on Day 1 of each next 28-day cycle starting with Cycle 2; and lazertinib 240 mg by mouth once daily from Cycle 1 Day 1.
6. Group 6:
-Same amivantamab SC-CF and lazertinib treatment as in Group 1 with addition of anticoagulant (to prevent blood clot in a vein) from Day 1 through Day 120.

Amivantamab doses will be based on body weight.

During the study, various tests will be performed that includes blood tests, physical examinations, ECG, ECOG, vital signs, eye tests, and questionnaires. All side effects will be recorded until study ends (up to 1 year and 5 months).

What are the possible benefits and risks of participating?
Benefits:
There is no established benefit to participants of this study. Based on scientific theory, amivantamab and lazertinib may result in killing of lung cancer cells. However, this cannot be guaranteed because amivantamab and lazertinib are still under investigation as a treatment and it is not known whether amivantamab and lazertinib will work.
Participants may experience some benefit from participation in the study that is not due to receiving study drug, but due to regular visits and assessments monitoring overall health.
Participation in the study may help other people with lung cancer in the future.
Risks:
Participants may have side effects from the drugs or procedures used in this study that may be mild to severe and even life-threatening, and these may vary from person to person. The most common, known risks of amivantamab and lazertinib are skin redness, nail inflammation, blood clots in the veins, lung damage and heart diseases. There are other, less frequent risks. The participant information sheet and informed consent form, which will be signed by every participant agreeing to participate in the study, includes a detailed section outlining the known risks to participating in the study.
Not all possible side effects and risks related to amivantamab and lazertinib are known at this moment. During the study, the Sponsor may learn new information about amivantamab and lazertinib. The study doctor will tell participants as soon as possible about any new information that might make them change their mind about being in the study, such as new risks.
To minimize the risk associated with taking part in the study, participants are frequently reviewed for any side effects and other medical events. Participants are educated to report any such events to the study doctor who will provide appropriate medical care. Any serious side effects that are reported to the Sponsor are thoroughly reviewed by a specialist drug safety team.

Amivantamab:
As of May 20, 2022, safety data are available for approximately 1055 patients who have received amivantamab.

Administration-Related Reactions:
When administered under the skin (subcutaneous administration), a side effect of amivantamab

that may occur during or shortly after an administration is completed is called an administration-related reaction. Administration-related reactions are expected during the first administration and are far less likely to occur during the following administrations.

Participants will receive premedication, including paracetamol/acetaminophen, an antihistamine, and a corticosteroid before the administration to help prevent or decrease any symptoms. Participants who don't have an administration-related reaction during their first administration may not need the corticosteroid before any future administrations but will still receive the paracetamol/acetaminophen and antihistamine.

Participants who have had an administration-related reaction and who have symptoms that may persist, may also get medications after the administration, including paracetamol /acetaminophen, an antihistamine, an anti-nausea medication, a corticosteroid, and other medications as needed for symptoms.

Rash:
Participants will be provided with instructions on how to prevent and treat rash. In addition, participants receiving both amivantamab and lazertinib will also be provided with prescriptions for more specific treatments if needed.

Lung Inflammation:
In patients treated with the combination of amivantamab and lazertinib, there have been cases of lung inflammation, including severe cases resulting in death.

Lazertinib:
Lazertinib is early in its development. As of May 20, 2022, safety data is available for approximately 770 patients who have received lazertinib.

Note: Male Participants, from when they start taking the study drug (amivantamab and lazertinib) until 6 months after the last dose, must use a condom when engaging in any activity that allows for the passage of ejaculate to another person.

Chemotherapy:

Other Medicines and Pemetrexed:
Medication for pain or inflammation (swelling), such as "nonsteroidal anti-inflammatory drugs" (NSAIDs), some of which can be purchased over the counter (i.e., ibuprofen) may affect the efficacy of pemetrexed and increase the risk of kidney injury or failure if taken at the same time. The immune system may become compromised while taking pemetrexed. As a result, live vaccines should be avoided.

Driving and Using Machines
Pemetrexed may make participants feel tired. Care must be taken when driving a car or using machines.

Carboplatin:
During treatment with carboplatin, participants will be given medicines which help reduce a potentially life-threatening complication known as tumour lysis syndrome, which is caused by chemical disturbances in the blood due to the breakdown of dying cancer cells that release their content to the bloodstream.

Driving and using machines:
Participants will be informed that they should not drive if they experience any side effect which may lessen their ability to do so such as nausea, vomiting, worsening of eyesight, or changes to their vision and hearing.

Risks / side effects from study tests:

Blood draw risk: Taking blood may cause bruising irritation at the place where the needle goes into the skin. Fainting, and in rare cases infection, may occur.

ECG: There is generally no risk with having an ECG.

MRI Risk (including Brain MRI): There are no known risks or side effects with having an MRI. If a contrast material is used, participants will be told about possible side effects or allergic reaction.

Intravenous (IV) line: Use of an intravenous line for study treatment administration, imaging and other tests may cause discomfort, irritation, minor bruising, bleeding, or injection leakage, and rarely causes nausea and light dizziness.

Imaging: Detailed information on the potential risks of ionising radiation will be included in the participant information.

Where is the study run from?
Janssen-Cilag International NV (Netherlands)

When is the study starting and how long is it expected to run for?
August 2022 to July 2026

Who is funding the study?
Janssen-Cilag International NV (Netherlands)

Who is the main contact?
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Contact information

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Clinical Trials Information System (CTIS)
2022-000526-21

Integrated Research Application System (IRAS)
1006215

ClinicalTrials.gov (NCT)
NCT05498428

Protocol serial number
61186372NSC2002, IRAS 1006215, CPMS 52118

Study information

Scientific Title
A phase 2, open-label, parallel cohort study of subcutaneous amivantamab in multiple regimens in patients with advanced or metastatic solid tumors including EGFR-mutated non-small cell lung cancer

Acronym
PALOMA-2

Study objectives
Current study hypothesis as of 27/06/2023:

The primary objectives are To assess the anticancer activity of the amivantamab subcutaneous formulation (amivantamab SC-CF) in combination treatment (all Groups except Group 4). and to characterize the safety of amivantamab SC-CF (Group 4).
Secondary objectives are :
1. To characterize the safety of amivantamab SC-CF (all Groups except Group 4).
2. To assess additional measures of anti-cancer activity of amivantamab SC-CF (all Groups except Group 4).
3. To evaluate the pharmacokinetics (what the body does to the drug) (all Groups except Group 4) of amivantamab.
4. To describe venous thromboembolic (VTE) (blood clot in veins) risk of amivantamab SC-CF and

lazertinib (all Groups except Group 4).
5. To assess and compare cancer therapy satisfaction and global impressions of symptom severity in participants treated with amivantamab IV and SC-CF (Group 4)

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Previous study hypothesis:

The primary objectives are to assess anti-tumor activity (objective response rate [ORR]) (Cohorts 1, 2, and 3) and to evaluate the safety (Cohort 4) of amivantamab SC-CF via manual injection.

Secondary objectives are to assess safety and additional measures of anti-tumor activity (Cohorts 1, 2, and 3) and to characterize the PK of amivantamab-SC-CF (Cohorts 1, 2, and 3). In Cohort 4 only, patient-reported outcomes (PROs) will be utilized to characterize participants' experience with both formulations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/11/2022, South Central - Hampshire B Ethics Committee (Temple Quay House, 2 The Square, Bristol Research Ethics Committee Centre, BS1 6PN, UK; +44 207 1048 088; hampshireb.rec@hra.nhs.uk), ref: 22/SC/0349

Study design
Interventional non-randomized parallel trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Advanced or Metastatic Solid Tumors including EGFR-mutated Non-Small Cell Lung Cancer.

Interventions
Current interventions as of 27/06/2023:

Experimental: Cohort 1 (Exon19/L858R NSCLC First Line [1L] Previously Untreated): Amivantamab + Lazertinib
Participants with treatment-naive locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring an epidermal growth factor receptor (EGFR) exon 19 deletion (exon19del) or exon 21 leucine 858 to arginine substitution (exon 21 L858R) mutation, will receive amivantamab SC-CF injection, 1600 milligrams (mg) and 2240 mg if body weight is greater than or equal to (>=) 80 kilograms (kg), on Cycle 1 Days 1, 8, 15, and 22 and on Days 1 and 15 of each subsequent 28-day cycle, starting with Cycle 2, along with lazertinib 240 mg orally once daily.

Experimental: Cohort 2 (Exon20 NSCLC, 1L Previously Untreated): Amivantamab + Pemetrexed + Carboplatin
Participants with treatment-naive locally advanced or metastatic NSCLC harboring an EGFR

exon20ins mutation will receive Amivantamab SC-CF injection 2560 mg and 3360 mg if body weight is >=80 kg on Cycle 1 Days 1, 8, and 15 and on Day 1 of each subsequent 21-day cycle, starting with Cycle 2 along with pemetrexed 500 milligrams per meter square (mg/m^2) as intravenous (IV) infusion (with vitamin supplementation) on Day 1 of each 21-day cycle and IV infusion carboplatin area under the concentration-time curve 5 milligrams per milliliters (mg/mL) per minute (AUC 5) maximum 750 mg on Day 1 of each 21-day cycle, for up to 4 cycles.

Experimental: Cohort 3 (Exon19/L858R NSCLC 2L Post Osimertinib):Amivantamab + Lazertinib+ Pemetrexed + Carboplatin
Participants with locally advanced or metastatic NSCLC harboring an EGFR exon19del or exon 21 L858R mutation who have experienced disease progression on or after treatment with a third-generation EGFR tyrosine kinase inhibitor (TKI) (osimertinib), will receive amivantamab SC-CF injection 2560 mg and 3360 mg if body weight is >=80 kg on Cycle 1 Days 1, 8, and 15 and on Cycle 1 Days 1, 8, and 15 and on Day 1 of each subsequent 21-day cycle, starting with Cycle 2 along with lazertinib 240 mg orally once daily, pemetrexed 500 mg/m^2 as an IV infusion (with vitamin supplementation) on Day 1 of each 21-day cycle up to 4 cycles, in combination with carboplatin for up to 4 cycles, then as maintenance until disease progression and IV infusion carboplatin area under the concentration-time curve 5 mg/mL per minute (AUC 5) maximum 750 mg on Day 1 of each 21-day cycle, for up to 4 cycles.
Lazertinib 240 mg by mouth once daily from Cycle 5 Day 1 when carboplatin treatment is completed, or sooner if carboplatin discontinued earlier than cycle 4.

Experimental: Cohort 4 (Previously Treated with Amivantamab IV): Switch from Amivantamab IV to SC-CF
Participants who were previously on amivantamab IV once every 2 weeks (Q2W) regimen as part of standard of care, for at least 3 months, either as monotherapy or combination with lazertinib, will receive amivantamab SC-CF injection 1600 mg and 2240 mg if body weight is greater than or equal to 80 kg in each 28 day cycle, Lazertinib 240mg orally once daily (where applicable)

Experimental: Cohort 5 (Exon19/L858R NSCLC First Line [1L] Previously Untreated): Amivantamab + Lazertinib
Participants with treatment-naive locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring an epidermal growth factor receptor (EGFR) exon 19 deletion (exon19del) or exon 21 leucine 858 to arginine substitution (exon 21 L858R) mutation will receive Amivantamab SC-CF 1600 mg/2240 mg (if BW ≥80 kg) on Cycle 1 Days 1, 8, 15, and 22, followed by 3200 mg /4320 mg (if BW ≥80 kg) on Day 1 of each next 28-day cycle starting with Cycle 2; and lazertinib 240 mg by mouth once daily from Cycle 1 Day 1.

Experimental: Cohort 6 (Exon19/L858R NSCLC First Line [1L] Previously Untreated): Amivantamab + Lazertinib
Participants with treatment-naive locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring an epidermal growth factor receptor (EGFR) exon 19 deletion (exon19del) or exon 21 leucine 858 to arginine substitution (exon 21 L858R) mutation will receive same amivantamab SC-CF and lazertinib treatment as in Group 1 with addition of anticoagulant (to prevent blood clot in a vein) from Day 1 through Day 120.

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Previous interventions:

Experimental: Cohort 1 (Exon19/L858R NSCLC First Line [1L] Previously Untreated): Amivantamab + Lazertinib

Participants with treatment-naive locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring an epidermal growth factor receptor (EGFR) exon 19 deletion (exon19del) or exon 21 leucine 858 to arginine substitution (exon 21 L858R) mutation, will receive amivantamab SC-CF injection, 1600 milligrams (mg) and 2240 mg if body weight is greater than or equal to (>=) 80 kilograms (kg), on Cycle 1 Days 1, 8, 15, and 22 and on Days 1 and 15 of each subsequent 28-day cycle, starting with Cycle 2, along with lazertinib 240 mg orally once daily.

Experimental: Cohort 2 (Exon20 NSCLC, 1L Previously Untreated): Amivantamab + Pemetrexed + Carboplatin
Participants with treatment-naive locally advanced or metastatic NSCLC harboring an EGFR exon20ins mutation will receive Amivantamab SC-CF injection 2560 mg and 3360 mg if body weight is >=80 kg on Cycle 1 Days 1, 8, and 15 and on Day 1 of each subsequent 21-day cycle, starting with Cycle 2 along with pemetrexed 500 milligrams per meter square (mg/m^2) as intravenous (IV) infusion (with vitamin supplementation) on Day 1 of each 21-day cycle and IV infusion carboplatin area under the concentration-time curve 5 milligrams per milliliters (mg/mL) per minute (AUC 5) maximum 750 mg on Day 1 of each 21-day cycle, for up to 4 cycles.

Experimental: Cohort 3 (Exon19/L858R NSCLC 2L Post Osimertinib):Amivantamab + Lazertinib+ Pemetrexed + Carboplatin
Participants with locally advanced or metastatic NSCLC harboring an EGFR exon19del or exon 21 L858R mutation who have experienced disease progression on or after treatment with a third-generation EGFR tyrosine kinase inhibitor (TKI) (osimertinib), will receive amivantamab SC-CF injection 2560 mg and 3360 mg if body weight is >=80 kg on Cycle 1 Days 1, 8, and 15 and on Cycle 1 Days 1, 8, and 15 and on Day 1 of each subsequent 21-day cycle, starting with Cycle 2 along with lazertinib 240 mg orally once daily, pemetrexed 500 mg/m^2 as an IV infusion (with vitamin supplementation) on Day 1 of each 21-day cycle up to 4 cycles, in combination with carboplatin for up to 4 cycles, then as maintenance until disease progression and IV infusion carboplatin area under the concentration-time curve 5 mg/mL per minute (AUC 5) maximum 750 mg on Day 1 of each 21-day cycle, for up to 4 cycles.

Experimental: Cohort 4 (Previously Treated with Amivantamab IV): Switch from Amivantamab IV to SC-CF
Participants who were previously on amivantamab IV once every 2 weeks (Q2W) regimen as part of standard of care, for at least 3 months, either as monotherapy or combination with lazertinib, will receive amivantamab SC-CF injection 1600 mg and 2240 mg if body weight is greater than or equal to 80 kg.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Lazertinib, amivantamab

Primary outcome(s)
1. Cohorts 1, 2, and 3: Objective Response Rate (ORR) Based on Investigator Assessment (INV) [Time Frame: Up to 1 year 6 months]
ORR based on INV will be reported. ORR is defined as the percentage of participants who achieve a complete response (CR) or partial response (PR), based on Response Evaluation

Criteria in Solid Tumors (RECIST) version 1.1, as determined by investigator.
2. Cohort 4: Number of Participants with Adverse Events (AEs) [Time Frame: Up to 1 year 6 months]
An AE is any untoward medical occurrence in a participant participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/ biological agent under study.
3. Cohort 4: Number of Participants with AEs by Severity [Time Frame: Up to 1 year 6 months]
An AE is any untoward medical occurrence in a participant participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/ biological agent under study. Severity of AEs will be graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) version 5.0. Severity scale ranges from Grade 1 (Mild) to Grade 5 (Death). Grade 1= Mild, Grade 2= Moderate, Grade 3= Severe, Grade 4= Life-threatening and Grade 5= Death related to adverse event.
4. Cohort 4: Number of Participants with Abnormalities in Clinical Laboratory Values [Time Frame: Up to 1 year 6 months]
Number of participants with abnormalities in clinical laboratory values (which includes serum chemistry, hematology, coagulation, urinalysis, and serology) will be reported.
5. Cohort 4: Number of Participants with Abnormalities in Clinical Laboratory Values by Severity [Time Frame: Up to 1 year 6 months]
Number of participants with laboratory values abnormalities which includes serum chemistry, hematology, coagulation, urinalysis, and serology) by severity will be reported. Severity of laboratory values abnormalities will be graded according to the NCI-CTCAE version 5.0. Severity scale ranges from Grade 1 (Mild) to Grade 5 (Death). Grade 1= Mild, Grade 2= Moderate, Grade 3= Severe, Grade 4= Life-threatening and Grade 5= Death related to adverse event.

Key secondary outcome(s))

1. Cohorts 1, 2, and 3: Number of Participants with AEs [Time Frame: Up to 1 year 6 months]
An AE is any untoward medical occurrence in a participant participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/ biological agent under study.
2. Cohorts 1, 2, and 3: Number of Participants with AEs by Severity [Time Frame: Up to 1 year 6 months]
An AE is any untoward medical occurrence in a participant participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/ biological agent under study. Severity of AEs will be graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) version 5.0. Severity scale ranges from Grade 1 (Mild) to Grade 5 (Death). Grade 1= Mild, Grade 2= Moderate, Grade 3= Severe, Grade 4= Life-threatening and Grade 5= Death related to adverse event.
3. Cohorts 1, 2, and 3: Number of Participants with Abnormalities in Clinical Laboratory Values [Time Frame: Up to 1 year 6 months]
Number of participants with abnormalities in clinical laboratory values (which includes serum chemistry, hematology, coagulation, urinalysis, and serology) will be reported.
4. Cohorts 1, 2, and 3: Number of Participants with Abnormalities in Clinical Laboratory Values by Severity [Time Frame: Up to 1 year 6 months]
Number of participants with abnormalities in clinical laboratory values which includes serum chemistry, hematology, coagulation, urinalysis, and serology) by severity will be reported. Severity of laboratory values abnormalities will be graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) version 5.0. Severity scale ranges from Grade 1 (Mild) to Grade 5 (Death). Grade 1= Mild, Grade 2= Moderate, Grade 3= Severe, Grade 4= Life-threatening and Grade 5= Death related to adverse event.
5. Cohorts 1, 2, and 3: ORR Based on Independent Central Review (ICR) [Time Frame: Up to 1

year 6 months]
ORR based on ICR will be reported. The ORR is defined as the percentage of participants who achieve a CR or PR, based on RECIST version 1.1, as confirmed by ICR.
6. Cohorts 1, 2, and 3: Duration of Response (DoR) [Time Frame: Up to 1 year 6 months]
DoR is defined as the time from the date of first documented response (PR or CR) until the date of documented progression or death, whichever comes first, for participants who have PR or CR.
7. Cohorts 1, 2, and 3: Time to Response (TTR) [Time Frame: Up to 1 year 6 months]
TTR (that is, time to first response) is defined as the time from the first dose of study treatment to the date of first documentation of a response (PR or CR) prior to any disease progression and subsequent anticancer therapy, based on RECIST version 1.1., for participants who have PR or CR as their best response.
8. Cohorts 1, 2, and 3: Clinical Benefit Rate (CBR) [Time Frame: Up to 1 year 6 months]
CBR is defined as the percentage of participants achieving CR or PR, or durable standard deviation (SD) of a duration of at least 11 weeks as defined by RECIST version 1.1.
9. Cohorts 1, 2, and 3: Progression-free Survival (PFS) [Time Frame: Up to 1 year 6 months]
The PFS is defined as the time from the first dose of study treatment until the date of objective disease progression or death, whichever comes first, based on RECIST version 1.1.
10. Overall Survival (OS) [Time Frame: Up to 1 year 6 months]
The OS is defined as the time from the first dose of study treatment until the date of death due to any cause.
11. Cohorts 1, 2, and 3: Serum Concentration Immediately Prior to the Next Dose Administration (Ctrough) of Amivantamab [Time Frame: Cycle 2 Day 1 of 28-day cycle]
Ctrough is defined as the serum concentration of amivantamab immediately prior to the next drug administration.
12. Cohort 4: Cancer Therapy Satisfaction as Assessed by Modified Therapy Administration Satisfaction Questionnaire - Intravenous (TASQ-IV) [Time Frame: Up to 1 year 6 months]
Cancer therapy satisfaction will be assessed using the modified TASQ-IV. The modified TASQ is a 12-item questionnaire measuring the impact of each mode of treatment administration on five domains: physical impact, psychological impact, impact on activities of daily living, convenience, and satisfaction. Each of the domain/scale scores is scored on a 1-100 scale, where 0 is worst and 100 is best.
13. Cohort 4: Cancer Therapy Satisfaction as Assessed by Modified Therapy Administration Satisfaction Questionnaire - Subcutaneous (TASQ-SC) [Time Frame: Up to 1 year 6 months]
Cancer therapy satisfaction will be assessed using the modified TASQ-SC. The modified TASQ is a 12-item questionnaire measuring the impact of each mode of treatment administration on five domains: physical impact, psychological impact, impact on activities of daily living, convenience, and satisfaction. Each of the domain/scale scores is scored on a 1-100 scale, where 0 is worst and 100 is best.
14. Cohort 4: Patient-reported Status as Assessed by Patient Global Impression of Change (PGIC) Scale Score [Time Frame: Up to 1 year 6 months]
Patient-reported status as assessed by PGIC scale score will be reported. The PGIC is an assessment of the participant's overall sense of whether there has been a change since starting treatment. The PGIC is a 7-point response scale. Participants will be asked to rate their current fatigue as compared to when they started the study, using the following 7-point scale: 1 = Much better, 2 = Moderately better, 3 = A little better, 4 = No change, 5 = A little worse, 6 = Moderately worse, and 7 = Much worse.
15. Cohort 4: Patient-reported Status as Assessed by Patient Global Impression of Symptom Severity (PGIS) Scale Score [Time Frame: Up to 1 year 6 months]
Patient-reported status as assessed by PGIS scale score will be reported. The PGIS is an assessment of lung cancer severity at a given point in time. The PGIS is a 5-point response scale. Participants will be asked to rate their fatigue over the past 7 days using the following 5-point scale: 1 = None, 2 = Mild, 3 = Moderate, 4 = Severe, and 5 = Very severe.

Completion date
01/07/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 27/06/2023:

Age:
1. Be ≥18 years of age (or the legal age of consent in the jurisdiction in which the study is taking place) at the time of informed consent.
Type of Participant and Disease Characteristics
2. Participant must have histologically or cytologically confirmed, locally advanced or metastatic, NSCLC, characterized at the time of locally advanced or metastatic disease diagnosis.

Additional Cohort specific disease requirements include:
Cohorts 1, 3, 5, 6: EGFR Exon19del or L858R mutation
Cohort 2: EGFR Exon 20ins mutation
EGFR Exon19del or Exon 21 L858R mutation (Cohort 1, 3, 5, 6) or EGFR Exon 20 insertion mutation (Cohort 2) must have been identified as determined by an FDA-approved or other validated test of either ctDNA or tumor tissue in a CLIA certified laboratory (sites in the US) or an accredited local laboratory (sites outside of the US). A copy of the initial test report documenting the EGFR mutation must be included in the participant records and a deidentified copy must also be submitted to the sponsor.
3. Have at least 1 measurable lesion, according to RECIST v1.1. If the only target lesion has been previously irradiated, it must show signs of disease progression since radiation was completed.

Prior Malignancies
4. May have a prior or concurrent second malignancy (other than the disease under study) which natural history or treatment is unlikely to interfere with any study endpoints of safety or the efficacy of the study treatment(s) (see Appendix 12 of the Protocol on Allowed Recent Second or Prior Malignancies for details).

Prior Therapy Restrictions or Requirements
5. Cohort-specific requirements with regards to prior therapy are as follows:
Cohort 1, 5 and 6:
Participant should not have received any prior systemic therapy for metastatic NSCLC.
Cohort 2: Participant should not have received any prior systemic therapy for metastatic NSCLC. However, prior monotherapy with an approved EGFR TKI targeting common EGFR mutations as first-line therapy for the treatment of locally advanced or metastatic disease is allowed, if: 1) treatment duration did not exceed 8 weeks; 2) lack of disease response was documented radiographically 3) associated toxicities have resolved to baseline; and 4) the EGFR TKI was discontinued at least 2 weeks or 4 half-lives prior to treatment initiation at C1D1, whichever is longer. Prior therapy with EGFR TKI agents targeting Exon20ins mutations (eg, TAK788 /mobocertinib or poziotinib), is not allowed.
Cohort 3:
Participant should have progressed on or after osimertinib monotherapy as the immediate prior line of systemic therapy. Osimertinib must have been administered as the first EGFR TKI for metastatic disease or as the second TKI after prior treatment with first- or second-generation EGFR TKI.

Cohort 4:
Participants need to currently be on an amivantamab IV Q2W regimen without dose reduction (1,050 mg or 1,400 mg depending on weight) as part of standard of care for at least 8 weeks, an expanded access program, or as a rollover from a long-term extension prior amivantamab Q2W study. No washout is required between IV and SC-CF administration.
6. Toxicities from prior anticancer therapy, if any, must have resolved to CTCAE Version 5.0 Grade 1 or baseline level (except for other toxicities as indicated in inclusion criteria 8, alopecia [any grade], Grade ≤2 peripheral neuropathy, and Grade <2 hypothyroidism stable on hormone replacement).
For Cohort 4 only:
Amivantamab related toxicities that are stable and deemed tolerable by the investigator and patient are not exclusionary.

Performance Status
7. Participant must have ECOG status of 0 or 1. Refer to Appendix 9 of the Protocol: Eastern Cooperative Oncology Group (ECOG) Performance Status.
Renal, Hepatic and Hematological Function
8. Participant must demonstrate adequate organ and bone marrow function required for safe administration of the cohort-specific regimen, without history of red blood cell transfusion or platelet transfusion within 7 days prior to the date of the laboratory test, as follows:
Cohorts 1, 4, 5, 6 (chemotherapy-free regimens):
8.1. Hemoglobin ≥9 g/dL
8.2. Absolute neutrophil count ≥1.5x109/L, without use of granulocyte colony stimulating factor (G-CSF) within 10 days prior to the date of the test
8.3. Platelets ≥75x109/L
8.4. ALT and AST ≤3xULN if no demonstrable liver metastases or ≤5xULN in the presence of liver metastases.
8.5. Total bilirubin ≤1.5xULN (participants with Gilbert's syndrome can enroll if conjugated bilirubin is within normal limits)
8.6. eGFR >50 mL/min as measured or calculated by MDRD (Appendix 11: Formulas for Estimating Glomerular Filtration Rate Using Modified Diet in Renal Disease Formula [in mL/min])
Cohorts 2 and 3 (chemotherapy regimens):
8.7. Hemoglobin ≥10 g/dL
8.8. Absolute neutrophil count ≥1.5x10^9/L, without use of G-CSF within 10 days prior to the date of the test
8.9. Platelets ≥100x10^9/L
8.10. ALT and AST ≤3 xULN if no demonstrable liver metastases or ≤5xULN in the presence of liver metastases.
8.11. Total bilirubin ≤1.5xULN (participants with Gilbert's syndrome can enroll if conjugated bilirubin is within normal limits)
8.12. eGFR>50 mL/min as measured or calculated by MDRD

HIV Status
9. Human immunodeficiency virus-positive participants are eligible if they meet all of the following:
9.1. No detectable viral load (ie, <50 copies/mL) at screening
9.2. CD4+ count >300 cells/mm3 at screening
9.3. No AIDS-defining opportunistic infection within 6 months of screening
9.4. Receiving HAART. Any changes in HAART due to resistance/progression should occur at least 3 months prior to screening. A change in HAART due to toxicity is allowed up to 4 weeks prior to

screening.
Note: HAART that could interfere with study treatment is excluded (consult the sponsor for a review of medications prior to enrollment).

Sex and Contraceptive/Barrier Requirements
10. A female participant of childbearing potential must have a negative serum pregnancy test at screening and within 72 hours of the first dose of study treatment and must agree to further serum or urine pregnancy tests during the study and for 6 months after the last dose of study treatment.
11. A female participant must be either of the following
11.1. Not of childbearing potential, or
11.2. Of childbearing potential and practicing at least 1 highly effective method of contraception contraception throughout the study and through 6 months after the last dose of study treatment.
Note: If a female participant becomes of childbearing potential after the start of the study, the female participant must comply with (11.2).
12. A female participant must agree not to donate eggs (ova, oocytes) or freeze for future use for the purposes of assisted reproduction during the study and for a period of 6 months after receiving the last dose of study treatment. Female participants should consider preservation of eggs prior to study treatment as anti-cancer treatments may impair fertility.
13. A female participant must agree not to be pregnant, breast feeding, or planning to become pregnant while enrolled in this study or within 6 months after the last dose of study treatment.
14. A male participant must wear a condom (with or without spermicide) when engaging in any activity that allows for passage of ejaculate to another person during the study and for 6 months after receiving the last dose of study treatment.
If the male participant's partner is a female of childbearing potential, the male participant must use condoms (with or without spermicide) and the female partner of the male participant must also be practicing a highly effective method of contraception (see Appendix 5: Contraceptive and Barrier Guidance). A male participant who is vasectomized must still use a condom, but the partner is not required to use contraception.
15. A male participant must agree not to donate sperm for the purposes of reproduction during the study and for 6 months after receiving the last dose of study treatment. Male participants should consider preservation of sperm prior to study treatment as anti-cancer treatments may impair fertility.

Informed Consent
16. Must sign an ICF (or their legally acceptable representative must sign if allowed per local regulation) indicating that the participant understands the purpose of, and procedures required for, the study and is willing to participate in the study.
17. Be willing and able to adhere to the lifestyle restrictions specified in this protocol. In addition, participants considered for Cohort 6 must be eligible for, and agree to comply with, the use of prophylactic anticoagulation with a direct oral anticoagulant or a low molecular weight heparin during the first 4 months of study treatment (from Day 1 through Day 120) according to NCCN or local guidelines

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Previous inclusion criteria:

Age:
1. Be ≥18 years of age (or the legal age of consent in the jurisdiction in which the study is taking place) at the time of informed consent.

Type of Participant and Disease Characteristics
2. Participant must have histologically or cytologically confirmed, locally advanced or metastatic, NSCLC, characterized at the time of locally advanced or metastatic disease diagnosis.

Additional Cohort specific disease requirements include:
Cohorts 1 and 3: EGFR Exon19del or L858R mutation
Cohort 2: EGFR Exon 20ins mutation
EGFR Exon19del or Exon 21 L858R mutation (Cohort 1 and 3) or EGFR Exon 20 insertion mutation (Cohort 2) must have been identified as determined by an FDA-approved or other validated test of either ctDNA or tumor tissue in a CLIA certified laboratory (sites in the US) or an accredited local laboratory (sites outside of the US). A copy of the initial test report documenting the EGFR mutation must be included in the participant records and a deidentified copy must also be submitted to the sponsor.
3. Have at least 1 measurable lesion, according to RECIST v1.1. If the only target lesion has been previously irradiated, it must show signs of disease progression since radiation was completed.

Prior Malignancies
4. May have a prior or concurrent second malignancy (other than the disease under study) which natural history or treatment is unlikely to interfere with any study endpoints of safety or the efficacy of the study treatment(s) (see Appendix 12 of the Protocol on Allowed Recent Second or Prior Malignancies for details).

Prior Therapy Restrictions or Requirements
5. Cohort-specific requirements with regards to prior therapy are as follows:
Cohort 1 and 2:
Participant should not have received any prior systemic therapy for metastatic NSCLC.
Cohort 2: Participant should not have received any prior systemic therapy for metastatic NSCLC. However, prior monotherapy with an approved EGFR TKI targeting common EGFR mutations as first-line therapy for the treatment of locally advanced or metastatic disease is allowed, if: 1) treatment duration did not exceed 8 weeks; 2) lack of disease response was documented radiographically 3) associated toxicities have resolved to baseline; and 4) the EGFR TKI was discontinued at least 2 weeks or 4 half-lives prior to treatment initiation at C1D1, whichever is longer. Prior therapy with EGFR TKI agents targeting Exon20ins mutations (eg, TAK788 /mobocertinib or poziotinib), is not allowed.
Cohort 3:
Participant should have progressed on or after osimertinib monotherapy as the immediate prior line of systemic therapy. Osimertinib must have been administered as the first EGFR TKI for metastatic disease or as the second TKI after prior treatment with first- or second-generation EGFR TKI.
Cohort 4:
Participants need to currently be on an amivantamab IV Q2W regimen without dose reduction (1,050 mg or 1,400 mg depending on weight) as part of standard of care for at least 3 months, an expanded access program, or as a rollover from a long-term extension prior amivantamab Q2W study. No washout is required between IV and SC-CF administration.
6. Toxicities from prior anticancer therapy, if any, must have resolved to CTCAE Version 5.0 Grade 1 or baseline level (except for other toxicities as indicated in inclusion criteria 8, alopecia [any grade], Grade ≤2 peripheral neuropathy, and Grade <2 hypothyroidism stable on hormone replacement).
For Cohort 4 only:
Amivantamab related toxicities that are stable and deemed tolerable by the investigator and patient are not exclusionary.

Performance Status
7. Participant must have ECOG status of 0 or 1. Refer to Appendix 9 of the Protocol: Eastern Cooperative Oncology Group (ECOG) Performance Status.
Renal, Hepatic and Hematological Function
8. Participant must demonstrate adequate organ and bone marrow function required for safe administration of the cohort-specific regimen, without history of red blood cell transfusion or platelet transfusion within 7 days prior to the date of the laboratory test, as follows:
Cohorts 1 and 4 (chemotherapy-free regimens):
8.1. Hemoglobin ≥9 g/dL
8.2. Absolute neutrophil count ≥1.5x109/L, without use of granulocyte colony stimulating factor (G-CSF) within 10 days prior to the date of the test
8.3. Platelets ≥75x109/L
8.4. ALT and AST ≤3xULN if no demonstrable liver metastases or ≤5xULN in the presence of liver metastases.
8.5. Total bilirubin ≤1.5xULN (participants with Gilbert's syndrome can enroll if conjugated bilirubin is within normal limits)
8.6. eGFR >50 mL/min as measured or calculated by MDRD (Appendix 11: Formulas for Estimating Glomerular Filtration Rate Using Modified Diet in Renal Disease Formula [in mL/min])

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 27/06/2023:

Medical Conditions
1. Participant has an uncontrolled illness, including but not limited to:
1.1. Uncontrolled diabetes
1.2. Ongoing or active infection (includes infection requiring treatment with antimicrobial therapy [participants will be required to complete antibiotics 1 week prior to starting study treatment] or diagnosed or suspected viral infection).
1.3. Active bleeding diathesis
1.4. Refractory nausea and vomiting, chronic gastrointestinal diseases, inability to swallow the

formulated product, or previous significant bowel resection that would preclude adequate absorption of study treatment
1.5. Psychiatric illness or any other circumstances (including social circumstances) that would limit compliance with study requirements
1.6. Any ophthalmologic condition that is clinically unstable
2. Participant has a medical history of ILD, including drug induced ILD or radiation pneumonitis
3. Participant has a history of hypersensitivity to any excipients of the investigational products to be used in their enrolment cohort
4. Participant has a history of clinically significant cardiovascular disease including, but not limited to:
4.1. All cohorts (regimens potentially including lazertinib) except Cohort 2: Diagnosis of deep vein thrombosis or pulmonary embolism within 1 month prior to the first dose of study treatment(s), or any of the following within 6 months prior to the first dose of study treatment (s): myocardial infarction, unstable angina, stroke, transient ischemic attack, coronary/peripheral artery bypass graft, or any acute coronary syndrome. Clinically non-significant thrombosis, such as nonobstructive catheter-associated clots, are not exclusionary.
4.2. All cohorts (regimens potentially including lazertinib) except Cohort 2: Participant has a significant genetic predisposition to venous thromboembolic events (VTE; such as Factor V Leiden).
4.3. All cohorts (regimens potentially including lazertinib) except Cohort 2: Participant has a prior history of VTE and is not on appropriate therapeutic anticoagulation as per NCCN or local guidelines.
4.4. Prolonged QTcF interval >480 msec or clinically significant cardiac arrhythmia or electrophysiologic disease (eg, placement of implantable cardioverter defibrillator or atrial fibrillation with uncontrolled rate).
4.5. Uncontrolled (persistent) hypertension: systolic blood pressure >160 mmHg; diastolic blood pressure >100 mmHg
4.6. Congestive heart failure defined as NYHA class III-IV or hospitalization for CHF (any NYHA class) [Appendix 8] within 6 months of treatment initiation at C1D1
4.7. Pericarditis/clinically significant pericardial effusion
4.8. Myocarditis
4.9. Baseline LVEF below the institution’s lower limit of normal at screening, as assessed by echocardiogram or MUGA scan.

5. Participant had major surgery (eg, requiring general anesthesia), excluding placement of vascular access or tumor biopsy, or had significant traumatic injury within 4 weeks before signing the ICF, or will not have fully recovered from surgery, or has surgery planned during the time the participant is expected to participate in the study.
Note: Participants with planned surgical procedures to be conducted under local anesthesia may participate.
6. Participant has uncontrolled tumor-related pain:
Symptomatic lesions amenable to palliative radiotherapy (eg, bone metastases, or metastases causing nerve impingement) should be treated more than 7 days prior to the treatment initiation at C1D1.
Disease Characteristics
7. Participant has received radiotherapy for palliative purposes less than 7 days prior to treatment initiation at C1D1.
8. Participant has symptomatic brain metastases. A participant with asymptomatic or previously treated and stable brain metastases may participate in this study. Participants who have received definitive radiation or surgical treatment for symptomatic or unstable brain metastases and have been clinically stable and asymptomatic for at least 2 weeks before Screening are eligible, provided they have been either off corticosteroid treatment

or are receiving low-dose corticosteroid treatment (≤10 mg/day prednisone or equivalent) for at least 2 weeks prior to treatment allocation.
9. Participant has a history of leptomeningeal disease, or participant has spinal cord compression not definitively treated with surgery or radiation.
Prior/Concomitant Therapy or Clinical Study Experience
10. Taken any disallowed therapies as noted in Section 6.8, Concomitant Therapy before the planned first dose of study treatment.
11. Participant has received a live or live attenuated vaccine within 3 months before Cycle 1 Day 1. The seasonal influenza vaccine and non-live vaccines against COVID 19 are not exclusionary.
12. For all cohorts (regimens potentially including lazertinib) except Cohort 2: Participant is currently receiving medications or herbal supplements known to be potent CYP3A4/5 inducers and is unable to stop use for an appropriate washout period prior to Cycle 1 Day 1.

Other Exclusions
13. Any condition for which, in the opinion of the investigator, participation would not be in the best interest of the participant (eg, compromise well-being) or that could prevent, limit, or confound the protocol-specified assessments
14. Participant previously enrolled in the Sponsor's studies 73841937NSC3003 (NCT04487080, MARIPOSA), 61186372NSC3001 (NCT04538664, PAPILLON) or 61186372NSC3002 (NCT04988295, MARIPOSA-2), or 61186372NSC3004 (NCT05388669, PALOMA-3).

Viral Hepatitis Assessments
15. Participant has at Screening any of the following:
Seropositive for hepatitis B: defined by a positive test for HBsAg. Participants with resolved infection (ie, participants who are HBsAg negative with antibodies to total anti-HBc with or without the presence of anti-HBs) must be screened using RT-PCR measurement of HBV DNA levels. Those who are RT-PCR positive will be excluded. Participants with serologic findings suggestive of HBV vaccination (antiHBs positivity as the only serologic marker) AND a known history of prior HBV vaccination, do not need to be tested for HBV DNA by RT-PCR
Positive hepatitis C antibody test result at screening or within 3 months prior to starting study treatment. NOTE: Participants with positive hepatitis C antibody due to prior resolved disease can be enrolled only if a confirmatory negative hepatitis C RNA test is obtained.
Positive hepatitis C RNA test result at screening or within 3 months prior to first dose of study treatment. NOTE: Test is optional and participants with negative hepatitis C antibody test are not required to also undergo hepatitis C RNA testing.
16. Other clinically active liver disease of infectious origin.

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Previous exclusion criteria:

Medical Conditions
1. Participant has an uncontrolled illness, including but not limited to:
1.1. Uncontrolled diabetes
1.2. Ongoing or active infection (includes infection requiring treatment with antimicrobial therapy [participants will be required to complete antibiotics 1 week prior to starting study treatment] or diagnosed or suspected viral infection).
1.3. Active bleeding diathesis
1.4. Refractory nausea and vomiting, chronic gastrointestinal diseases, inability to swallow the formulated product, or previous significant bowel resection that would preclude adequate absorption of study treatment
1.5. Psychiatric illness or any other circumstances (including social circumstances) that would

limit compliance with study requirements
1.6. Any ophthalmologic condition that is clinically unstable
2. Participant has a medical history of ILD, including drug induced ILD or radiation pneumonitis
3. Participant has a history of hypersensitivity to any excipients of the investigational products to be used in their enrolment cohort
4. Participant has a history of clinically significant cardiovascular disease including, but not limited to:
4.1. Diagnosis of deep vein thrombosis or pulmonary embolism within 1 month prior to the first dose of study treatment(s), or any of the following within
6 months prior to the first dose of study treatment(s): myocardial infarction, unstable angina, stroke, transient ischemic attack, coronary/peripheral artery bypass graft, or any acute coronary syndrome. Clinically non-significant thrombosis, such as non-obstructive catheter-associated clots, are not
exclusionary.
4.2. Prolonged QTcF interval >480 msec or clinically significant cardiac arrhythmia or electrophysiologic disease (eg, placement of implantable cardioverter defibrillator or atrial fibrillation with uncontrolled rate).
4.3. Uncontrolled (persistent) hypertension: systolic blood pressure >160 mmHg; diastolic blood pressure >100 mmHg
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4.5. Pericarditis/clinically significant pericardial effusion
4.6. Myocarditis
4.7. Baseline LVEF below the institution’s lower limit of normal at screening, as assessed by echocardiogram or MUGA scan.
5. Participant had major surgery (eg, requiring general anesthesia), excluding placement of vascular access or tumor biopsy, or had significant traumatic injury within 4 weeks before signing the ICF, or will not have fully recovered from surgery, or has surgery planned during the time the participant is expected to participate in the study.
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8. Participant has symptomatic brain metastases. A participant with asymptomatic or previously treated and stable brain metastases may participate in this study. Participants who have received definitive radiation or surgical treatment for symptomatic or unstable brain metastases and have been clinically stable and asymptomatic for at least 2 weeks before Screening are eligible, provided they have been either off corticosteroid treatment
or are receiving low-dose corticosteroid treatment (≤10 mg/day prednisone or equivalent) for at least 2 weeks prior to treatment allocation.
9. Participant has a history of leptomeningeal disease, or participant has spinal cord compression not definitively treated with surgery or radiation.
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11. Participant has received a live or live attenuated vaccine within 3 months before Cycle 1 Day 1. The seasonal influenza vaccine and non-live vaccines against COVID 19 are not exclusionary.

12. Cohorts 1, 3, and 4 (regimens potentially including lazertinib): Participant is currently receiving medications or herbal supplements known to be potent CYP3A4/5 inducers and is unable to stop use for an appropriate washout period prior to Cycle 1 Day 1.
Other Exclusions
13. Any condition for which, in the opinion of the investigator, participation would not be in the best interest of the participant (eg, compromise well-being) or that could prevent, limit, or confound the protocol-specified assessments

Date of first enrolment
20/10/2022

Date of final enrolment
01/09/2025

Locations

Countries of recruitment
United Kingdom

England

Scotland

Australia

Brazil

China

India

Israel

Japan

Malaysia

Spain

Taiwan

Türkiye

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
Lothian
Scotland
EH4 2XU

Study participating centre
Torbay Hospital
Newton Road
Torquay
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TQ2 7AA

Study participating centre
Uclh
250 Euston Road
London
England
NW1 2PQ

Study participating centre
University Hospitals of Leicester NHS Trust
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Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
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Southwick Hill Road
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Portsmouth
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PO6 3LY

Study participating centre
Cheltenham General Hospital
Sandford Road
Cheltenham
England
GL53 7AN

Sponsor information

Organisation
Janssen-Cilag International NV

Funder(s)

Funder type
Industry

Funder Name
Janssen-Cilag International NV

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing policy of the Janssen Pharmaceutical Companies of Johnson and Johnson is available at www.janssen.com/clinical- trials/transparency. As noted on this site, requests for access to the study data can be submitted through Yale Open Data Access (YODA) Project site at yoda.yale.edu

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes