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A study of JNJ-90301900 in combination with chemoradiation followed by consolidation immunotherapy for non-small cell lung cancer (NSCLC)

Submission date
14/05/2025

Recruitment status
Recruiting

Registration date
07/07/2025

Overall study status
Ongoing

Last Edited
22/08/2025

Condition category
Cancer

[X] 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
Non-small cell lung cancer (NSCLC) is the most common type of lung cancer with about 20% being locally advanced disease Stage III (that is, large tumours or disease that has spread to nearby lymph nodes), of which approximately 80% cannot be removed by surgery. First-line treatment for participants with locally advanced Stage III NSCLC has been concurrent platinum-based doublet chemotherapy with radiation therapy (cCRT); however, this was associated with poor treatment outcomes.
JNJ-90301900 is an intratumoural drug that is injected directly into the tumour and subsequently activated by radiation therapy to enhance tumour cell death without increasing the radiation effects in adjacent non-injected healthy tissues.
In this study, researchers want to assess if JNJ-90301900 as a radioenhancer added to cCRT followed by cIT can improve objective response rate (ORR; that is percentage of participants in a study who have complete or partial response to treatment within a certain period) and safety of JNJ-90301900 in participants with locally advanced and unresectable NSCLC.

Who can participate?
Patients aged 18 years and over with non-small cell lung cancer (NSCLC)

What does the study involve?
Part 1:
Participants will receive JNJ-90301900 injected intratumorally and/or intranodally (Cohort A: 22% gross tumor volume [GTV] and Cohort B: 33% GTV) along with cCRT (concurrent chemotherapy with radiation therapy), followed by consolidation immunotherapy (cIT) to evaluate the feasibility of the JNJ-90301900 injection procedure.

Part 2:
Participants will receive JNJ-90301900 injected intratumorally and/or intranodally (Arm A: 22% GTV and Arm B: 33% GTV) along with cCRT followed by cIT to evaluate the effectiveness and

safety of JNJ-90301900.
Arm C: Control treatment: Participants will receive treatment with cCRT followed by cIT as a control treatment to evaluate the effectiveness and safety of JNJ-90301900.

All participants will be followed up until 24 months after the last treatment of cCRT, unless participant withdrawal, loss to follow-up, death, or end of study.

What are the possible benefits and risks of participating?
There is no established benefit to participants of this study. Based on scientific theory, taking JNJ-90301900 may potentiate the effects of radiation therapy within cancer tissues in a controlled manner. However, this cannot be guaranteed because JNJ-90301900 is still under investigation as a treatment, and it is not known whether JNJ-90301900 will work.
In addition, if participants are enrolled into the control treatment group, they will not receive JNJ-90301900 and will receive standard of care concurrent platinum-based doublet chemotherapy with radiation therapy (cCRT) along with chemotherapy with carboplatin and paclitaxel only followed by consolidation immunotherapy (cIT) by durvalumab during this study. Participants may experience some benefit from participation in the study that is not due to receiving the study drug but may be due to regular visits and assessments monitoring overall health. Participation in the study may help other people with stage III lung cancer in the future. Participants may have side effects from the study drugs or procedures used in this study. The severity of these side effects may vary from person to person and may even be life-threatening. The most common, known risks are getting symptoms such as tachycardia (rapid and irregular heartbeat), upper abdominal pain, nausea, asthenia, fatigue, feeling hot, night sweats, anxiety, presyncope (feeling fainting), Low or high blood pressure, hypersensitivity (exaggerated or inappropriate response of the immune system), pain at injection site and risk of toxicity to other organs after getting the study drug or control treatment. There are other, less frequent risks.

Where is the study run from?
Johnson And Johnson Enterprise Innovation Inc. (Netherlands)

When is the study starting and how long is it expected to run for?
May 2025 to December 2028

Who is funding the study?
Johnson And Johnson Enterprise Innovation Inc. (Netherlands)

Who is the main contact?
Dr Jack Brady, jbrady16@its.jnj.com

Plain English summary under review with external organisation

Contact information

Type(s)
Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1011086

Protocol serial number
90301900NSC2001, CPMS 64732

Study information

Scientific Title
A Phase II, randomized, open-label, active-controlled study of JNJ-90301900 in combination with chemoradiation followed by durvalumab in locally advanced and unresectable stage III NSCLC

Acronym
CONVERGE

Study objectives
Primary objectives:
To determine whether JNJ-90301900 as a radioenhancer added to concurrent platinum-based doublet chemotherapy with radiation therapy (cCRT) followed by consolidation immunotherapy (cIT) can improve objective response rate (ORR; that is percentage of participants in a study who have a complete or partial response to the treatment within a certain period of time) in

participants with locally advanced stage IIIA & IIIB non-small cell lung cancer (NSCLC) that cannot be removed by surgery.

Secondary objectives:
To evaluate the following in participants treated with JNJ-90301900 in combination with cCRT:
1. Additional clinical benefit to the participants from treatment
2. The locoregional and distant effects of JNJ-90301900 (that is, cancer is in the same place as the original cancer or has spread elsewhere)
3. Safety and tolerability

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/07/2025, London Bridge Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8229 ; londonbridge.rec@hra.nhs.uk), ref: 25/LO/0407

Study design
Interventional randomized parallel group controlled trial

Primary study design
Interventional

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Locally advanced and unresectable Stage III non-small cell lung cancer

Interventions
Experimental: Part 1: Cohort A and Cohort B
Participants will receive JNJ-90301900 injected intratumorally and/or intranodally (cohort A: 22% gross tumor volume [GTV] and cohort B: 33% GTV) along with cCRT (concurrent chemotherapy with radiation therapy), followed by consolidation immunotherapy (cIT) to evaluate the feasibility of the JNJ-90301900 injection procedure.

Experimental: Part 2: Arm A and Arm B
Participants will receive JNJ-90301900 injected intratumorally and/or intranodally (Arm A: 22% GTV and Arm B: 33% GTV) along with cCRT followed by cIT to evaluate the efficacy and safety of JNJ-90301900.

Active Comparator: Part 2: Arm C: (Control treatment)
Participants will receive treatment with cCRT followed by cIT as a control treatment to evaluate the efficacy and safety of JNJ-90301900.

Randomization will be performed electronically via an IVRS vendor. Patients will be stratified by the following factors: programmed death-ligand 1 (PD-L1) status (≥1% versus <1%) and NSCLC staging (IIIA versus IIIB).

All participants will be followed up until 24 months after the last treatment of cCRT, unless participant withdrawal, loss to follow-up, death, or end of study.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
JNJ-90301900 [Hafnium Oxide]

Primary outcome(s)
Objective Response Rate (ORR) using Independent Central Review (ICR) assessment. ORR is defined as the percentage of participants who have a best response of complete response (CR) or partial response (PR) according to Response Evaluation Criteria in Solid Tumours (RECIST) version (v) 1.1 using ICR assessments. The timeframe for evaluation is up to 2 years and 2 months.

Key secondary outcome(s))
Timeframe for evaluation is up to 12 weeks (DRR post-cCRT and pre-cIT and DCR post-cCRT and pre-cIT) and 2 years and 2 months for all other measures:
1. Disease response rate (DRR) post-cCRT and pre-cIT
2. Disease control rate (DCR) post-cCRT and pre-cIT
3. Objective response rate (ORR) as assessed by the Investigator according to RECIST v1.1
4. Progression-free survival (PFS)
5. Duration of response (DoR)
6. Time to locoregional failure (LRF)
7. Time to distant failure (DF)
8. Number of participants with treatment-emergent adverse events (TEAEs) related to study treatment
9. Number of participants reporting laboratory parameters, physical examination, vital signs, including Eastern Cooperative Oncology Group (ECOG) Performance Status abnormalities

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Must be a candidate for standard of care (SOC) treatment of non-small cell lung cancer (NSCLC) by concurrent platinum-based doublet chemotherapy with radiation therapy (cCRT) followed by consolidation durvalumab treatment, as determined by the investigator and per local guidelines at screening
2. Have a medical history of pathologically (histologically or cytologically) proven diagnosis of NSCLC within 3 months prior to enrolment/randomisation
3. Have locally advanced unresectable stage IIIA or IIIB NSCLC according to the eighth edition lung cancer stage classification
4. Have at least one target lesion (primary lung lesion or involved lymph node[s]) per RECIST version 1.1 that is amenable to intratumoral and/or intranodal injection and external beam

radiation therapy (EBRT), as determined by the investigator at screening
5. Have an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 1

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Medical history of:
1.1. Primary immunodeficiency
1.2. Organ transplant that requires therapeutic immunosuppression
2. Any of the following within 3 months prior to enrolment/randomisation:
2.1. Severe or unstable angina
2.2. Myocardial infarction
2.3. Major thromboembolic events
2.4. Clinically significant ventricular arrhythmias
2.5. Heart failure classified as New York Heart Association (NYHA) functional class III to IV
3. Another concurrent or prior primary malignancy (other than NSCLC) within the last 36 months at informed consent
4. Known allergies, hypersensitivity, or intolerance to any ingredients of JNJ-90301900 crystalline solution, platinum-based doublet chemotherapy (ChT), or durvalumab
5. Active bleeding diathesis or requirement for therapeutic anticoagulation or antiplatelet therapy that cannot be interrupted or altered for procedures

Date of first enrolment
01/10/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

Australia

Brazil

China

France

Hong Kong

Netherlands

Spain

Study participating centre
Not provided at time of registration
United Kingdom
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Sponsor information

Organisation
Johnson & Johnson (Netherlands)

Funder(s)

Funder type
Industry

Funder Name
Johnson and Johnson

Alternative Name(s)
Johnson & Johnson, Johnson & Johnson Services, Inc., Johnson&Johnson, Johnson & Johnson Private Limited, , , J&J, JNJ

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date