Targeted therapy improves clinical outcomes in patients with advanced NSCLC. This approach is to assess somatic mutations in circulating cell-free tumor DNA (cfDNA) for patients with newly diagnosed metastatic non-squamous NSCLC.

The aim of this study is to demonstrate that cfDNA has performance comparable to that of tissue-based genotyping for the task of detecting clinically actionable tumor biomarkers in patients with newly diagnosed metastatic non-squamous NSCLC.

The SLLIP study is funded by Guardant Health, Inc., Redwood City, CA USA.

PROSPECTIVE COMPARISON OF LIQUID BIOPSY TO STANDARD OF CARE TISSUE TESTING IN METASTATIC, NON-SQUAMOUS, NSCLC PATIENTS: SPANISH LUNG LIQUID VS. INVASIVE BIOPSY PROGRAM

THE SLLIP STUDY

#1384TP

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REFERENCES


5. Tumor tissue testing for genetic alterations is performed according to local standard of care. Per the Central Laboratory (Pangaea Oncology S.A.), archived pre-treatment tissue samples (if available) are sent to an external central laboratory (Pangaea Oncology S.A.).

6. Treatment decisions are made according to local standard of care.

7. Tumor response is assessed centrally per RECIST v1.1.

8. This is a Spanish multi-center, prospective, single-cohort study.

9. Peripheral blood (20 mL) is collected in Streck™ cell preservation tubes for cfDNA sequencing prior to treatment initiation.

10. Additional blood is collected two weeks after treatment initiation and at disease progression (or at 12 months if no progression).

11. cfDNA sequencing is performed using Guardant360, Guardant Health Inc., Redwood City USA.

12. Tumor tissue testing for genetic alterations is performed according to local standard of care.

13. Treatment decisions are made according to local standard of care.

14. Archived pre-treatment tissue samples (if available) are sent to an external central laboratory (Pangaea Oncology S.A.).

15. Tumor response is assessed centrally per RECIST v1.1.

Table 1: Eligibility criteria

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
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<tbody>
<tr>
<td>1. Patients with biopsy proven, metastatic, previously untreated, non-squamous NSCLC. Patients may have received adjuvant cytotoxic chemotherapy, but not targeted neo-adjuvant or adjuvant therapy.</td>
<td>1. Any concurrent, non-cutaneous, malignancy (i.e., the exception of early stage non-invasive cervical cancer). Any prior cancer must have occurred more than 5 years prior with no evidence of currently active disease.</td>
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<td>2. Age ≥ 18 years.</td>
<td>2. Pregnancy.</td>
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<td>3. Ability to provide written informed consent.</td>
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<td>4. Willingness to provide blood sample at three time points.</td>
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<td>5. Standard-of-care tissue genotyping ordered.</td>
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</table>

The sample size for the study is 182 patients. This number gives a 65% probability (under reasonable hypotheses) that the observed detection rate (sensitivity) for the liquid assay will be no more than 2% lower than the corresponding detection rate for the tissue test.

The SLIP study is funded by Guardant Health, Inc., Redwood City, CA USA.

STATISTICAL DESIGN


5. Tumor tissue testing for genetic alterations is performed according to local standard of care.

6. Treatment decisions are made according to local standard of care.

7. Archived pre-treatment tissue samples (if available) are sent to an external central laboratory (Pangaea Oncology S.A.).

8. Tumor response is assessed centrally per RECIST v1.1.

REFERENCES


