

# OCEANiC: A Phase II, Open-label, Multi-centre Clinical Trial of Osimertinib With or Without Adjuvant Chemotherapy Guided by Tumour NGS Co-mutation Status and ctDNA Detection in Patients With Stage IIA-III A EGFR-Mutant Non Small Cell Lung Cancer Following Complete Surgical Resection

ACTRN12623000552684

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Status	RECRUITING
Phase	Phase 2
Sponsor	The University of Sydney
Enrollment	100 participants

## Plain Language Summary

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Non-small cell lung cancer (NSCLC) with an EGFR mutation is a type of lung cancer that responds well to targeted drugs. Osimertinib is a medication that directly targets this mutation and has shown strong results in reducing the risk of cancer returning after surgery. However, the standard approach also includes chemotherapy, which brings its own side effects.

The OCEANiC trial is testing whether it is safe for some patients to skip chemotherapy entirely and take osimertinib alone — using sophisticated DNA testing of the tumour tissue and blood samples to identify which patients are truly low risk for recurrence. High-risk patients will still receive both chemotherapy and osimertinib. The aim is to spare low-risk patients unnecessary treatment without compromising their outcomes.

You may be eligible if you are 18 or older, have had complete surgical removal of Stage IIA–III A NSCLC with an EGFR mutation, have recovered well from surgery within the past 8 weeks, and have adequate organ function. You must not have received prior systemic treatment for your lung cancer. A brain MRI is required as part of the screening process.

## Key Eligibility Criteria

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### Inclusion (25)

- Adults, aged 18 years or older, with histological diagnosis of NSCLC. Patients with mixed small cell lung cancer histology are not eligible.
- Stage IIA to IIIA NSCLC according to AJCC 8th edition.
- Complete surgical resection of the primary NSCLC is mandatory.
- All gross tumour surgically removed at the end of surgery.
- All surgical resection margins must be microscopically negative.

... and 20 more (see full listing online)

### Exclusion (17)

- Previous diagnosis of another lung cancer within 5 years prior to registration.
- Prior systemic treatment for NSCLC including prior EGFR pathway inhibitor treatment.
- History of hypersensitivity to active or inactive excipients of osimertinib or drugs with a similar chemical structure or class to osimertinib.
- Post-operative radiotherapy (PORT) planned.
- Prior radiation to lung and/or mediastinum.

... and 12 more (see full listing online)

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<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12623000552684>

### Locations (11 total)

This information is provided for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [anzctr.org.au](http://anzctr.org.au). Generated by [ClinicalTrialsFinder.org](http://ClinicalTrialsFinder.org).

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Peter MacCallum Cancer Centre - Melbourne, NSW,QLD,SA,WA,VIC, Australia  
St Vincent's Hospital (Melbourne) Ltd - Fitzroy, NSW,QLD,SA,WA,VIC, Australia  
Austin Health - Austin Hospital - Heidelberg, NSW,QLD,SA,WA,VIC, Australia  
... and 8 more locations