上海医生团队发表晚期肺癌治疗新成果：患者生存期有望延长10个月

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上海医生团队发表晚期肺癌
治疗新成果：患者生存期有望延长10个月
。肺癌可以分为小细胞肺癌和非小细胞肺癌，后者约占肺癌的85%。而在非小细胞肺癌中，有一类EGFR突变的患者治疗效果不太理想，比如EGFR
L858R突变的患者，或确诊时已发生脑转移的患者。

为解决上述治疗难题，上海市胸科医院肿瘤科学术带头人陆舜教授及科主任李子明团队牵头开展一项临床研究，将阿美替尼与含铂双药化疗“ 强强联合 ”，并与阿美替尼单药治疗形成对照组。开展了一项名为“ AENEAS
2 ”的研究。研究结果显示，联合治疗模式整整让患者生存期延长了10个月。

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Aumolertinib with or without chemotherapy in EGFR-mutated advanced non-small-cell lung cancer (AENEAS2): an open-label, multicentre, randomised, controlled, phase 3 trial

Ziming Li, Jie Hu,* Jianhua Chen, Yan Yu, Xiangjiao Meng, Xiaorong Dong, Yanping Hu, Yinghua Ji, Haifeng Liu, Weibo Wang, Fangling Ning, Zhihong Zhang, Chunling Liu, Zhiye Zhang, Qiming Wang, Wei Zheng, Honghai Wang, Xiujuan Qu, Zhenming Chen, Shaonan Fan, Xiaoqing Zhang, Shun Lu*

Summary

Background Although third-generation epidermal growth-factor receptor (EGFR)-tyrosine-kinase inhibitors (TKIs) are standard first-line therapies for patients with advanced EGFR-mutated non-small-cell lung cancer (NSCLC), their effectiveness is often limited by the emergence of drug resistance and subsequent disease progression. Given the previously established clinical efficacy and adverse event profile of aumolertinib, we aimed to evaluate the efficacy and adverse event profile of aumolertinib in combination with platinum-based chemotherapy versus aumolertinib monotherapy as first-line treatment for patients with locally advanced or metastatic NSCLC patients with EGFR-sensitive mutations.

Methods The open-label, multicentre, randomised, controlled, phase 3 AENEAS2 trial was done across 60 hospitals in China. Patients aged at least 18 years with Eastern Cooperative Oncology Group performance status (ECOG PS) 0–1; treatment-naive; histologically or cytologically confirmed locally advanced or metastatic NSCLC harbouring EGFR-sensitive mutations (ex19del/L858R with or without other EGFR mutations) were eligible. Brain metastases were allowed if neurologically stable. Previous EGFR-TKI therapy was an exclusion criterion. Patients were randomly assigned (1:1) with block randomisation (block size of 6), stratified by EGFR mutation type and baseline brain metastasis, to receive aumolertinib monotherapy (110 mg orally once a day) or combination therapy (aumolertinib 110 mg orally once a day plus pemetrexed 500 mg/m² intravenously with cisplatin [75 mg/m²] or carboplatin [area under the plasma concentration–time curve 5] intravenously on day 1 of 21-day cycles for 4–6 cycles), followed by maintenance therapy (aumolertinib 110 mg orally once a day and pemetrexed 500 mg/m² intravenously once every 3 weeks). The primary endpoint was progression-free survival assessed by blinded independent central review (BICR; RECIST version 1.1). Efficacy was analysed in the full-analysis set, which included all randomly assigned patients, and safety was analysed in patients who received at least one dose of the actual trial treatment. The trial is registered at ClinicalTrials.gov, NCT04923906, and is ongoing, but closed to enrolment.

Findings Between Aug 4, 2021, to June 18, 2024, of 1011 patients assessed for eligibility, 624 randomly assigned patients (median age 59·0 years [IQR 52·0–66·0]; 337 [54%] were female, 287 [46%] were male) were randomly assigned. 310 (50%) patients received combination therapy and 314 (50%) received monotherapy. As of the data cutoff date (June 18, 2024), the median follow-up was 23·4 months (IQR 20·5–26·5). In the full-analysis set, median BICR-assessed progression-free survival was 28·9 months (95% CI 26·3, NA) in the combination therapy versus 18·9 months (17·8–21·1) in the monotherapy (hazard ratio [HR] 0·47, 95% CI 0·37–0·60; log-rank p<0·0001). The most common grade 3–4 adverse events (occurring in at least 20% in any group) were neutrophil count decreased (168 [55%] of 304 in the combination group versus four [1%] of 316 in monotherapy group), white blood cell count decreased (103 [34%] *vs* one [<1%]), and platelet count decreased (62 [20%] *vs* two [1%]). Serious adverse events occurred in 109 (36%) patients in the combination group and 53 (17%) in the monotherapy group, the most common of which were platelet count decreased (22 [7%] *vs* 0), neutrophil count decreased (17 [6%] *vs* 0), white blood cell count decreased (13 [4%] *vs* 0), and anaemia (ten [3%] *vs* two [1%]). Treatment-related deaths occurred in one (<1%) patient in the combination group (encephalopathy) and two (1%) in the monotherapy group (pulmonary embolism and respiratory failure with circulatory collapse).

Interpretation Aumolertinib in combination with chemotherapy significantly improved progression-free survival. Although this regimen was associated with increased toxicity, the side-effects were managed with dose adjustment and supportive treatment aligned with clinical practice. Long-term follow-up is required to assess overall survival. The AENEAS2 study provides evidence to guide clinical practice regarding EGFR-TKIs and their combination use in treating patients with advanced EGFR-mutated NSCLC.

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*Joint first authors

For the Chinese translation of the abstract see Online for appendix 1

Shanghai Lung Cancer Center, Department of Medical Oncology, Shanghai Chest Hospital, Shanghai JiaoTong University, School of Medicine, Shanghai, China (Prof Z Li MD, Prof S Lu MD PhD); Department of Respiratory Medicine, Shanghai Geriatric Medical Center, Shanghai, China (Prof J Hu MD PhD); Zhongshan Hospital Fudan University, Shanghai, China (Prof J Hu); Department of Medical Oncology, Hunan Cancer Hospital, Changsha, China (Prof J Chen MD); Department of Respiratory Medicine, Cancer Hospital Affiliated to Harbin Medical University, Harbin, China (Prof Y Yu MD); Cancer Hospital of Shandong First Medical University (Shandong Cancer Institute, Shandong Cancer Hospital), Jinan, China (Prof X Meng MD); Department of Oncology, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China (Prof X Dong MD); Department of Medical Oncology, Hubei Cancer Hospital, Wuhan, China (Y Hu MS); Department of Medical Oncology, the First Affiliated Hospital of Xinxiang Medical University, Xinxiang, China (Prof Y Ji PhD); Jilin Cancer Hospital, Changchun, China (H Liu MS); Shandong Provincial Hospital Affiliated to Shandong First Medical University, Jinan, China

这项研究在线发表于国际顶级医学期刊《柳叶刀·肿瘤学》。上海市胸科医院供图

2026年6月22日，澎湃新闻记者从上海市胸科医院获悉，上述这项研究近期在线发表于国际顶级医学期刊《柳叶刀·肿瘤学》（The Lancet Oncology）。该研究为晚期肺癌患者一线联合治疗提供了精准化的策略，填补了国内原研肺癌靶向药物联合治疗领域的空白。其中，李子明是本文的第一作者，陆舜是本文的通讯作者。

研究团队介绍，此项研究在全国60家中心进行，共纳入624例既往未经治疗的EGFR敏感突变局部晚期或转移性非小细胞肺癌患者，随机分配接受阿美替尼联合含铂化疗或阿美替尼单药治疗。



上海市胸科医院肿瘤科学术带头人陆舜教授正联合团队为患者会诊。上海市胸科医院供图

研究结果显示，联合治疗组的中位无进展生存期达到了28.9个月，而单用靶向药组为18.9个月，延长了10个月。同时，联合治疗将疾病进展或死亡风险降低了53%。更令人鼓舞的是，在此次研究中，对于L858R突变和有脑转移的这两类患者来说，联合治疗方案同样显示出明确的生存获益。研究还提示，阿美替尼联合化疗可能为脑转移患者带来有前景的颅内疗效。这为此类既往疗效不佳的患者提供了强有力的治疗新选择。在安全性方面，研究结果也表现良好，患者耐受度较高。

此次AENEAS 2研究的发表具有重要的临床意义，这也是目前唯一基于中国原研三代EGFR靶向药

且全部入组中国人群的同类III期研究。该研究为中国晚期非小细胞肺癌患者的一线联合治疗策略，提供了高质量的“本土证据”，同时也持续提升中国原创治疗方案在全球指南中的影响力，为肺癌患者带来更多新的治疗选择和长期生存希望。

作者：陈斯斯 来源：澎湃新闻

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