# Pembrolizumab Improves Overall Survival in Locally Advanced Cervical Cancer

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Locally advanced cervical cancer presents a significant clinical challenge, with current standard-of-care chemoradiotherapy offering limited long-term survival benefits for many patients. The ENGOT-cx11/GOG-3047/KEYNOTE-A18 trial investigated whether integrating the immune checkpoint inhibitor pembrolizumab into this regimen could improve patient outcomes. This report details the overall survival findings from the second interim analysis of this pivotal Phase 3 study.

**KEY TAKEAWAYS**

- The Pivot: Pembrolizumab, when added to chemoradiotherapy, significantly improved overall survival in locally advanced cervical cancer.
- The Data: The 36-month overall survival rate was 82.6% with pembrolizumab plus chemoradiotherapy, compared to 74.8% with placebo plus chemoradiotherapy (HR 0.67; 95% CI 0.50-0.90; p=0.0040).
- The Action: This immuno-chemoradiotherapy strategy is supported as a new standard of care for patients with newly diagnosed, high-risk, locally advanced cervical cancer.

## Background and Rationale

Locally advanced cervical cancer remains a challenging malignancy, with chemoradiotherapy (CRT) as the established standard of care. Despite CRT, a substantial proportion of patients experience disease progression or recurrence, highlighting the need for more effective treatment strategies. Immunotherapy, particularly with PD-1 inhibitors like pembrolizumab, has demonstrated efficacy in various cancers by enhancing the body's immune response against tumor cells. The ENGOT-cx11/GOG-3047/KEYNOTE-A18 study was designed to evaluate whether the addition of pembrolizumab to concurrent CRT, followed by adjuvant pembrolizumab, could improve progression-free survival (PFS) and overall survival (OS) in patients with newly diagnosed, high-risk, locally advanced cervical cancer. The first interim analysis previously reported a statistically significant and clinically meaningful improvement in PFS with the pembrolizumab combination1.

## Study Design and Methods

This was a randomised, double-blind, placebo-controlled, phase 3 trial (ENGOT-cx11/GOG-3047/KEYNOTE-A18) conducted across 176 sites in 30 countries. Eligible patients had newly diagnosed, high-risk, locally advanced cervical cancer, defined as FIGO 2014 stage IB2-IIB with node-positive disease or stage III-IVA regardless of nodal status. Histological confirmation of squamous cell carcinoma, adenocarcinoma, or adenosquamous cervical cancer was required. Patients were randomly assigned 1:1 to receive either pembrolizumab (200 mg) or placebo intravenously every

3 weeks for five cycles concurrently with CRT (cisplatin and radiotherapy), followed by 15 cycles of pembrolizumab (400 mg) or placebo every 6 weeks. Stratification factors at randomisation included planned external beam radiotherapy type (IMRT/VMAT vs. non-IMRT/non-VMAT), cervical cancer stage (FIGO 2014 stage IB2-IIB node positive vs. III-IVA), and planned total radiotherapy dose (<70 Gy vs. ≥70 Gy equivalent dose of 2 Gy). Primary endpoints were progression-free survival (PFS) per RECIST 1.1 by investigator or histopathological confirmation, and overall survival (OS) defined as time from randomisation to death from any cause. Safety was a secondary endpoint1.

## Key Findings: Overall Survival Benefit

Between June 9, 2020, and December 15, 2022, a total of 1060 patients were randomised: 529 to the pembrolizumab-chemoradiotherapy group and 531 to the placebo-chemoradiotherapy group. At the second interim analysis, with a median follow-up of 29.9 months (IQR 23.3-34.3), the study met its primary objective for overall survival. Median overall survival was not reached in either treatment arm. The 36-month overall survival rate was 82.6% (95% CI 78.4-86.1) in the pembrolizumab group, compared to 74.8% (95% CI 70.1-78.8) in the placebo group. This translated to a hazard ratio for death of 0.67 (95% CI 0.50-0.90; p=0.0040), indicating a 33% reduction in the risk of death with the addition of pembrolizumab1.

## Safety Profile

Regarding safety, grade 3 or higher adverse events occurred in 413 (78%) of 528 patients in the pembrolizumab-chemoradiotherapy group and 371 (70%) of 530 patients in the placebo-chemoradiotherapy group. The most common grade 3 or higher adverse events in both groups included anaemia, decreased white blood cell count, and decreased neutrophil count. Potentially immune-mediated adverse events were observed in 206 (39%) of patients receiving pembrolizumab-chemoradiotherapy, compared to 90 (17%) in the placebo-chemoradiotherapy group1.

## Clinical Implications

The significant improvement in overall survival observed with the addition of pembrolizumab to chemoradiotherapy, building upon previously reported progression-free survival benefits, suggests a meaningful advance in the management of high-risk, locally advanced cervical cancer. These findings support the integration of pembrolizumab into the treatment paradigm for this patient population. The safety profile, while showing an increase in immune-mediated adverse events with pembrolizumab, is generally consistent with the known safety profile of PD-1 inhibitors in combination with chemotherapy and radiation, requiring careful monitoring and management.

## Why this matters for clinical practice today

For clinicians managing locally advanced cervical cancer, these results provide compelling evidence for a new treatment strategy that can extend patient lives. The 36-month overall survival rate of over 82% with pembrolizumab represents a substantial improvement over historical outcomes with chemoradiotherapy alone. While the increased incidence of immune-mediated adverse events necessitates vigilance and experience in managing such toxicities, the survival benefit appears to outweigh these risks for eligible patients. This study underscores the evolving role of immunotherapy in solid tumors and establishes a strong foundation for considering pembrolizumab as a new standard of care in this specific high-risk setting.

## Limitations and Next Steps

While the study demonstrates a significant overall survival benefit, the median follow-up of 29.9 months is relatively short, and longer-term follow-up will be crucial to fully understand the durability of the response and potential late-onset toxicities. The study population focused on high-risk locally advanced cervical cancer, and further research may be needed to determine the applicability of this regimen to other stages or risk profiles. Future investigations could also explore biomarkers to identify patients most likely to benefit from this immuno-chemoradiotherapy approach and to further refine toxicity management strategies. The study was funded by Merck Sharp & Dohme, a subsidiary of Merck & Co1.

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## REFERENCES

1. 1. Lorusso D, Xiang Y, Hasegawa K, et al. Pembrolizumab or placebo with chemoradiotherapy followed by pembrolizumab or placebo for newly diagnosed, high-risk, locally advanced cervical cancer (ENGOT-cx11/GOG-3047/KEYNOTE-A18): overall survival results from a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet. 2024;404(10460):1321-1332. doi:10.1016/S0140-6736(24)01808-7

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