

FULL TEXT LINKS

Randomized Controlled Trial *Int J Cancer*. 2026 Jan 1;158(1):172-181. doi: 10.1002/ijc.70094.

Epub 2025 Aug 16.

A multicenter randomized controlled trial of intrapleural perfusion of methotrexate-loaded tumor cell-derived microparticles combined with systemic therapy for malignant pleural effusion

Cheng Zeng¹, Yujing Tan¹, Zhimin Jiao², Sheng Hu³, Sanyuan Tang⁴, Qingming Shi⁵, Tianan Yi⁶, Jiming Chen⁷, Mei Cai⁸, Hu Liu⁹, Xinyan Liu¹⁰, Jingyan Zhu¹¹, Ping Sun¹², Yan Zhang¹³, Ting Zhu¹⁴, Hongyan Jin¹⁵, Zhiyu Wang¹⁶, Mengxian Zhang¹⁷, Guohua Yu¹⁸, Jiani Wang¹, Fei Ma¹

Affiliations

PMID: 40818045 DOI: [10.1002/ijc.70094](https://doi.org/10.1002/ijc.70094)

Abstract

This study evaluated the efficacy and safety of intrapleural perfusion with methotrexate-loaded tumor cell-derived microparticles (MTX-TMPs) combined with systemic therapy (ST) in patients with malignant pleural effusion (MPE) secondary to lung or breast cancer. In this multicenter, randomized, open-label trial, 102 patients were assigned 1:1 to receive either MTX-TMPs intrapleural perfusion (50 mL daily for 4 days) plus ST (cohort 1) or interleukin-2 (IL-2) intrapleural perfusion (50 mL every 3 days for three sessions) plus ST (cohort 2). The objective response rate (ORR) and disease control rate (DCR) of pleural effusion were evaluated in 91 patients (50 in cohort 1, 41 in cohort 2). ORR was significantly higher in cohort 1 than in cohort 2 (76.0% vs. 53.7%, $p = 0.025$), as was DCR (92.0% vs. 70.7%, $p = 0.012$). Among 83 patients included in the survival analysis, the median overall survival (OS) was 15.0 months (95% CI: 9.2-26.9) in cohort 1 and 6.9 months (95% CI: 5.3-15.8) in cohort 2 (HR = 0.75; 95% CI: 0.46-1.24; $p = 0.266$). One-, two-, and three-year OS rates in cohort 1 were 55.3%, 36.2%, and 25.5%, compared to 38.9%, 25.0%, and 25.0% in cohort 2. Both regimens showed manageable safety profiles, with anemia, pyrexia, fatigue, leukopenia, gastrointestinal symptoms, and liver dysfunction being the most common treatment-related adverse events. These findings suggest that intrapleural perfusion of MTX-TMPs combined with ST represents a promising and safe strategy for the management of MPE in patients with lung or breast cancer.

Keywords: interleukin-2; malignant pleural effusion; methotrexate-loaded tumor cell-derived microparticles; objective response rate; treatment-related adverse events.

© 2025 UICC.

[PubMed Disclaimer](#)

Related information

[MedGen](#)[PubChem Compound \(MeSH Keyword\)](#)

LinkOut - more resources

Full Text Sources

[Ovid Technologies, Inc.](#)[Wiley](#)

Medical

