

# Clinical trial: New dual therapy could revolutionize treatment of urothelial and bladder cancers

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Dr. Alison Zhang. Credit: Macquarie University

An international clinical trial of a treatment for advanced urothelial cancer has found a new dual therapy can nearly double patients' life expectancy.

The new immunotherapy is a combination of two drugs—enfortumab vedotin (EV) and pembrolizumab—delivered by infusion, and it is now being submitted to [regulatory authorities](#) for approval as a first-line, or primary, treatment for advanced urothelial cancer.

If approved, it would represent the first significant change in treatment for urothelial and [bladder cancer](#) in 30 years.

A total of 886 patients at 50 sites worldwide took part in EV-302, a randomized Phase 3 trial to compare the effectiveness of the EV-pembrolizumab combination with that of [chemotherapy](#) in patients with locally advanced or metastatic [urothelial carcinoma](#).

Urothelial carcinoma is the term for a group of aggressive cancers affecting the bladder and parts of the urothelial tract, including the cells lining the ureter and parts of kidneys.

Bladder cancer is the most common of these and every year more than 573,000 people globally and about 3,100 Australians are diagnosed with the devastating disease. Most people diagnosed are over the age of 60, and about 75% are male.

Macquarie University Hospital (MUH) was the only site in NSW and one of just six in Australia to take part in the EV-302 trial. Nine MUH patients participated.

Macquarie Medical Oncologist Dr. Alison Zhang was the principal chief investigator at MUH, working with associate investigator and Macquarie University Director of Clinical Trials, Professor Howard Gurney, and a team of researchers and trials staff.

Dr. Zhang says the [findings](#), which were presented at the European Society for Medical Oncology ([ESMO](#)) [Congress 2023](#), are ground-

breaking.

"This represents a major milestone in treatment, with the potential to revolutionize [patient care](#)," she says.

"Until now, the most effective treatment available has been chemotherapy, with a combination of the drugs cisplatin and gemcitabine, but even with treatment, the survival rate is poor.

"There have been dozens of trials over the years trying to improve on that, without success.

"Compared to chemotherapy, the EV-pembrolizumab combination has doubled the median progression-free time from 6.3 months to 12.5 months, and nearly doubled the median overall survival time from 16.1 months to 31.5 months."

Sixty-eight percent of patients in the trial had shrinkage of their cancer with the EV-pembrolizumab combination compared to 44% of patients who received chemotherapy.

Of the patients who received the [new therapy](#), 29.1% experienced a complete response, compared to 12.5% of chemotherapy patients.

Dr. Zhang, says complete response is not always synonymous with cure, as urothelial cancer is an aggressive disease.

"However, this therapy could still mean long-term remission for many patients, and the results support it becoming the new standard of care for urothelial [cancer](#)," she says.

Provided by Macquarie University

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