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## **MEDIA RELEASE**

Tuesday, 24 February 2026

# **STRIVE clinical trial now available in Aotearoa New Zealand to improve outcomes in vulvar cancer**

The Australian New Zealand Gynaecological Oncology Group (ANZGOG) in partnership with the Canadian Cancer Trials Group (CCTG) announces the local opening of the STRIVE clinical trial – *Stratification of Vulvar Squamous Cell Carcinoma by HPV and p53 status to Guide Excision* clinical trial (CCTG Protocol VU.2; ANZGOG Protocol ANZGOG2109/2021).

STRIVE represents an important step forward in advancing evidence-based surgical management for women diagnosed with vulvar squamous cell carcinoma (VSCC).

### **About the STRIVE Trial**

STRIVE is an international, prospective, stratification study designed to refine surgical decision-making for patients with *primary vulvar squamous cell carcinoma* (VSCC) based on tumour biology. The study is led globally by the CCTG and led in Aotearoa New Zealand by ANZGOG with Professor Paul Cohen and Dr Lois Eva serving as the ANZ Study Co-Chairs.

VSCC is the most common form of vulvar cancer (>90% of cases), primarily affecting postmenopausal women. It arises via two main pathways: HPV-associated or HPV-independent, with the latter often linked to chronic inflammatory conditions like lichen sclerosus. Symptoms include persistent itching, bleeding, and ulcerated lesions, typically on the labia.

The primary objective of STRIVE is to estimate 3-year local recurrence rates in patients with HPV-associated (HPV-A) and HPV-independent (HPV-I) VSCC who are surgically managed according to differentiated vulvar intraepithelial neoplasia (dVIN) / p53 status and tumour margin clearance. The findings are expected to inform stratified surgical approaches and support personalised care pathways.

During the past few years, it has become obvious that vulval cancers that arise from Human Papilloma Virus (HPV- Associated) behave in a different way than vulval cancers that arise from lichen sclerosus (an autoimmune disease) (HPV – Independent) and that they are less aggressive and have a better prognosis (outcome) with fewer recurrences. This may mean therefore that HPV- Associated cancers may require less aggressive treatment and do not need such wide margins or repeat surgery. Studies that have looked at existing practices think that less surgery is safe in these tumours, but it has not been formally studied in a trial. Less surgery would mean fewer complications, better function and less disfiguring surgery.

There is also recent evidence that with HPV independent tumours arising from lichen sclerosus, if the underlying conditions that lead to cancer are present at the edge of the tissue when it is removed (abnormalities in a gene called p53 and pre-cancerous changes called differentiated vulval intraepithelial neoplasia – dVIN) then this may lead to more recurrences of the cancer. The result of all this information means that we are unsure which is the best way to treat the two different cancers and the STRIVE Study has been designed to try and answer these questions.



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Early-stage vulvar cancer that is HPV-associated may not require more treatment after initial surgery based on a laboratory assessment of the tumour tissue. The study hopes to learn if this approach will result in fewer side effects by avoiding additional surgery and will not increase the risk of the cancer coming back. Conversely, early-stage vulvar cancer that is HPV-independent may require more surgery after initial surgery based on a laboratory assessment of the tumour tissue. The study hopes to learn if this approach will decrease the risk of your cancer coming back.

### **Significance for Clinical Practice**

Data from STRIVE will address critical gaps in the understanding of biological determinants of recurrence in VSCC. By evaluating outcomes based on HPV status and molecular markers such as p53, the study aims to:

- Improve risk stratification for surgical management
- Reduce rates of local recurrence
- Support evidence-based margin assessment
- Strengthen clinical guidelines for VSCC treatment
- Promoting personalised treatment approaches for vulvar cancers

Given the relative rarity of vulvar cancer, international collaboration is essential. The STRIVE trial brings together global expertise to enhance clinical evidence and improve outcomes for women affected by this disease.

**Eligibility Criteria:** Adult women diagnosed with *primary vulvar squamous cell carcinoma (VSCC)* FIGO stage I–II disease

### **Study Activation and Site Information**

#### **International Launch:**

- STRIVE opened in *Canada on 1 October 2024*.
- To date, *eight international sites are open and 13 participants have been enrolled*.

#### **Australia and Aotearoa New Zealand:**

- The first Australasian site at *Auckland City Hospital* officially opened on *30 January 2026* and is currently actively recruiting with Dr Lois Eva serving as Principal Investigator.

#### **Clinical Trial Registration:**

- *ClinicalTrials.gov*: **NCT06358469** — <https://clinicaltrials.gov/study/NCT06358469>
- *ANZCTR*: Currently being updated; link available upon request

**Attachments:** Trial schema and study overview (refer to email attachment).

### **Contact and Further Information**

Members of the media or clinical research community seeking further details are encouraged to contact:

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#### **About ANZGOG**

The Australia New Zealand Gynaecological Oncology Group (ANZGOG) is the peak national gynaecological cancer research organisation for Australia and New Zealand. Our mission is to improve outcomes and quality of life for everyone with a lived experience of gynaecological cancer by conducting and promoting clinical trials and multidisciplinary research.