TPS5637 Poster Session

Stratification of vulvar squamous cell carcinoma (VSCC) by HPV and P53 status to guide excision: CCTG VU.2 STRIVE study (NCT06358469).

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Background: Early VSCC is treated surgically. The optimal approach to margin re-excision may depend on molecular subtype. HPV associated (HPV-A) VSCC has a good outcome and is radiosensitive; HPV independent (HPV-I) p53 abnormal(p53abn) VSSC has a worse outcome and is less radiosensitive. **Methods:** Prospective, international, multicentre, phase II platform study enrolling participants with VSCC stratified by HPV status: HPV- Associated (HPV-A) vs HPV-Independent (HPV-I). Criteria: Key eligibility: Primary diagnosis VSCC; surgically staged I-II (FIGO 2021), molecular/ tumour features known: HPV, margin assessment for tumour clearance, dVIN (differentiated-type vulvar intraepithelial neoplasia), p53. Key ineligibility: tumour HPV-I p53 wild-type, recurrent VSCC, stage III-IV, non squamous histotype, planned or previous RT or chemotherapy. Treatment arms: Cohort HPV-A: Margin negative for cancer but < 8mm (regardless of high grade squamous intra epithelial lesion): Active surveillance (AS). Cohort HPV-I p53abn margin: negative for cancer but <8 mm and/or positive for dVIN and/or positive p53abn: 2:1 randomization to re-excision versus AS. Primary objective: To estimate the 3-year local recurrence rate (LRR) for HPV-A and HPV-I VSCC surgically managed based on dVIN/p53 status, tumour margin clearance. Secondary objectives: recurrence free and disease specific survival, OS, economics, patient reported outcomes. Statistical design: Cohort HPV-A: n=120 enrolled over 3 years; the upper limit of a one-sided 95% CI for 3-year LRR would be 26% when the observed 3-year LRR=20%. Interim analyses (IAs) planned at 12, 24, 36 months after 1st enrollment and final analysis (FA) at 3 years after last enrollment. Cohort HPV-I: n=129, including 10% loss to follow-up, randomized over 3 years to re excision and surveillance arms in 2:1 ratio. 86 on re-excision arm would have at least 85% power with 95% confidence to exclude a 40% 3-year LRR in favour of a lower rate of 25%, while 43 on surveillance arm will enable an estimate of 3-year LRR at an accuracy that the half length of a two-sided 90% CI will be less than 13% when the observed rate is 40%. IA planned at 36 months after 39th patient enrolled to re-excision arm and FA at 3 years after last enrollment. Conduct to Date: This trial was activated Oct 1, 2024. Two enrollments as of Jan 19 2025. Supported by CCS grant #707213; CIHR #195984. Clinical trial information: NCT06358469. Research Sponsor: Canadian Cancer Society (CCS); 707213; Canadian Institutes of Health Research (CIHR); 195984.