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LONG TERM RESULTS FROM RT3VIN: A MULTI-CENTRE, RANDOMISED, PHASE II TRIAL OF CIDOFOVIR OR IMIQUIMOD TREATMENT FOR VULVAL INTRAEPITHELIAL NEOPLASIA 3

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Background
Vulval intraepithelial neoplasia (VIN) is a chronic vulval skin condition, which, if left untreated, may become cancerous. Currently the standard treatment for patients with VIN is surgery, but this does not guarantee a cure and can cause physical and psychological problems in women of reproductive age. The RT3 VIN trial demonstrated that topical treatment with cidofovir and imiquimod are effective in 46% of patients with acceptable levels of adverse events. This study reports the long-term (24 month) follow up of these patients as well as the long-term safety data.

Methods
Participants with complete response to treatment with either cidofovir or imiquimod were followed up for a further 24 months. All statistical analyses were pre-planned and conducted using Stata SE 14

Findings
The length of follow up was the same in each trial arm and was a median of 18.4 months (95% CI: 18.1-19.0 overall). At 18 months, 50% on imiquimod (95% CI: 33.6%-64.5%) and 69% of patient on cidofovir (95% CI: 51.2-82.0) remained lesion free. At 18 months, 71.6% on imiquimod (95% CI: 52.0-84.3) and 94% of patient on cidofovir (95% CI: 78.2-98.5) remained VIN free. There were no grade 4+ adverse events during follow up. There was no difference between trial arms in either the proportion of patients experiencing any grade 2+ adverse event during follow up (imiquimod: 24/42 (57%) vs. cidofovir: 27/41 (66%), $\chi 2=0.665$, $p=0.415$) or any grade 3+ during follow up (imiquimod: 3/42 (7%) vs. cidofovir: 6/41 (15%), $\chi 2=1.204$, $p=0.272$).

Interpretation
Long-term data indicates that response is maintained for longer following treatment with cidofovir compared to imiquimod with no difference in the rates of adverse events between the two drugs. Overall, the levels of adverse events and the absence of grade 4 events indicates acceptable safety of use of these drugs in this setting.