## DOES THE HPV-16/18 AS04-ADJUVANTED VACCINE BENEFIT WOMEN WITH CERVICAL DISEASE?

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**Objectives:** The AS04-adjuvanted human papillomavirus (HPV)-16/18 vaccine shows high prophylactic vaccine efficacy (VE) against cervical intraepithelial neoplasia (CIN)2+ associated with HPV-16/18. We investigated whether women who underwent subsequent cervical excision during the PATRICIA (NCT00122681) trial benefited from reduced incidence of new genital disease following vaccination in the end-of-study analysis.

**Methods:** Women aged 15–25 years, irrespective of baseline HPV/DNA-status, serostatus, or cytology, were randomised to receive HPV-16/18 vaccine (n=9,319) or hepatitis A vaccine (control; n=9,325) at Months 0, 1 and 6. Cervical samples were collected every 6 months for HPV DNA typing; gynaecological and cytological examinations (with histological sample when necessary) were performed annually. Incidence rates (IR; women with ≥1 event ≥60 days post-treatment per 100 person-years follow-up) and VE with 95% confidence intervals are reported for women who underwent surgical therapy (loop electrosurgical excision procedure [LEEP], cone, knife or laser) in the total vaccinated cohort (women receiving ?1 vaccine dose, regardless of baseline characteristics). All analyses are irrespective of HPV type.

**Conclusions:** 190 women in the HPV-16/18 vaccine group and 264 in the control group underwent surgical therapy. The number with subsequent CIN2+ (CIN2, CIN3, adenocarcinoma *in situ*, or invasive cervical cancer) ≥60 days after treatment of a first cervical lesion was 1 in the HPV-16/18 vaccine group and 9 in the control group. The IR of CIN2+ post-surgery was 0.24 (0.01–1.32) and 2.01 (0.92–3.81) for the HPV-16/18 vaccine and control groups, respectively. VE against CIN2+ was 88.2% (14.8–99.7). The number of women with CIN1+ (CIN1 or CIN2+) ≥60 days after treatment was 12 in the HPV-16/18 vaccine group and 22 in the control group. The IR of CIN1+ post-surgical therapy was 2.91 (1.50–5.08) for the HPV-16/18 vaccine group and 5.07 (3.18–7.68) for the control group. VE against CIN1+ was 42.6% (-21.1–74.1). Women who undergo surgical therapy after vaccination with the HPV-16/18 vaccine can continue to benefit due to reduction in the risk of developing further or recurrent CIN1+ or CIN2+ lesions.