Early salpingectomy with delayed oophorectomy as alternative for risk-reducing salpingo-oophorectomy – the first 2000 participants in the ongoing international TUBA-WISP II study

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Introduction:

Women with an increased inherited risk for ovarian carcinoma (OC) advised to undergo a risk-reducing salpingo-oophorectomy (RRSO) around the age of 40, which induces premature menopause. Combining the consequences of premature menopause with the hypothesis that high-grade serous carcinoma (HGSC) originates in the fallopian tubes, generates interest for an early risk-reducing salpingectomy (RRS) with delayed oophorectomy (DO) as an alternative strategy. The prospective international TUBA-WISP II study aims to investigate oncological safety of the alternative RRS/DO by comparing this strategy to the standard RRSO among pathogenic variant (PV) carriers with an increased risk for OC.

Methods:

Women who complete childbearing choose between RRSO or alternative RRS/DO. The primary aim is to prove non-inferiority of RRS/DO compared to RRSO in *BRCA1/2* PV carriers with the cumulative OC incidence at target age 46 (*BRCA1*) and 51 (*BRCA2).* This is recorded by performing a yearly PALGA search for Dutch participants and a yearly phone call for other participants.

Preliminary Results:

The first 2000 of the aimed 3000 participants, from 45 centers in 11 countries have been included. There were 1035 (51.7%) *BRCA1* PV- and 916 (45.8%) *BRCA2* PV carriers. Ratio between RRS/DO and RRSO is 1518 (75.9%) versus 482 (24.1%). At first surgery, eight HGSC's have been diagnosed, four in the RRS/DO group and four in the RRSO group. We found seven isolated STIC's in the RRS/DO group and three in the RRSO group. No OC has been diagnosed after first surgery in both groups so far. However, women are too young and follow-up is too short to draw any conclusions on these data.

Conclusion:

The study will continue recruitment to investigate whether RRS/DO is non-inferior compared to RRSO regarding safety in preventing OC. This multicenter international study demonstrates how a pathology database like PALGA can significantly enhance feasibility and execution of a large clinical trial.