

Trial sets new standard regimen for women with uterine carcinosarcomas

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Results from the phase III NRG Oncology clinical trial GOG 0261 comparing paclitaxel plus carboplatin (PC) to paclitaxel plus ifosfamide (PI) in women with stage I-IV, recurrent carcinosarcoma of the uterus or ovary, indicate that the PC combination treatment should be considered a standard of care for this patient population. The study concludes that among uterine cancer patients treatment with PC was not inferior to PI based on the primary objective overall survival (OS), and PC was associated with longer progression-free survival (PFS) outcomes when compared with PI. These results were recently presented at the American Society for Clinical Oncology (ASCO) Annual Meeting and was awarded a "Best of ASCO" designation.

"While they are rare, gynecologic carinosarcomas are extremely aggressive and there has been a great deal of debate surrounding what the ideal or optimal <u>treatment</u> regimen would be for the <u>women</u> who have these malignancies," stated Matthew A. Powell, MD, of the Washington University School of Medicine and the lead author of the NRG-GOG 0261 abstract. "Previous Phase 2 research suggested that paclitaxel combined with carboplatin may improve outcomes for this patient population in terms of safety and convenience of treatment, so we tested this against a treatment regimen that included paclitaxel and ifosfamide."

Results from the NRG GOG 0261 clinical trial including 449 eligible patients in the primary uterine carcinosarcoma cohort estimate median overall survival at 37 months for those who received PC compared to 29



months for the PI treatment arm (HR = 0.87; 90% CI = 0.70 to 1.075; p 0.1 for superiority (S). Additionally, median PFS was 16 months for women who received PC and 12 months for women who received PI (HR = 0.73; p = patients with ovarian carcinosarcoma with30 month median OS on the PC arm versus 25 months on the PI arm and 15 months median PFS for the PC arm and 10 months for the PI arm.

"The hope is to continue to improve survival and quality of life outcomes for women who experience this rare malignancy," added Dr. Powell.

More information: Powell MA, Filiaci VL, Hensley ML, Huang HQ, Moore KN, TewariKS, Copeland LJ, Secord AA, Mutch DG, Santin A, Richards W, Warshal DP, Spirtos NM, Disilverstro P, Ioffe O, Miller DS. A randomized phase 3 trial of paclitaxel (P) plus carboplatin (C) versus paclitaxel plus ifosfamide (I) in chemotherapy-naive patients with stage I-IV, persistent or recurrent carcinosarcoma of the uterus or ovary: An NRG oncology trial. Abstract presented at the annual meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL.

Provided by NRG Oncology

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