

# Phase III randomized pilot study comparing interferon $\alpha$ -2b in combination with radiation therapy versus radiation therapy alone in patients with stage III-B carcinoma of the cervix

Yazigi, Roberto

Aliste, G.

Torres, R.

Ciudad, A. M.

Cuevas, M.

Garrido, J.

Prado, S.

Solá, A.

Castillo, R.

Cerda, B.

Cumsille, M. A.

Gonzalez, M.

Navarro, C.

Reyes, J. M.

This randomized pilot study was designed to determine whether the addition of interferon  $\alpha$ -2b to standard radiation therapy offered an advantage in loco-regional control and survival over radiation therapy alone in a homogeneous group of patients with stage IIIB carcinoma of the cervix. Thirty-six patients were treated with a combination of interferon  $\alpha$ -2b plus radiation therapy, and 38 patients were treated with radiation therapy alone. Patients with evidence of ureteral obstruction were excluded from the study. Evaluation of loco-regional response was determined by pelvic examination, cervical cytology, biopsies and CT scans when indicated. Survival time was measured from initiation of treatment to date of death or last follow-up. Patient characteristics were comparable between both study arms. The objective complete response rate was 67% in the combined therapy

group and 55% in the radiation alone group ( $P = 0.454$ ). With a median follow-up of 17 months for all patients and 31 months