

18 Nov 1971

FROM: SGHSG

SUBJ: Clinical Investigation Proposal #339: Evaluation of Systemic Immunocompetence in Patients Receiving Local Irradiation Following Radical Mastectomy

TO: SGS (John J. McPhaul, Jr., Col, USAF, MC)

Reference SGPARG ltr dated 2 Nov 71 and SGS ltr dated 10 Nov 71, subject Investigation.

Para 2.a. (SGPAR ltr): Do the subjects operated on elsewhere and referred to WHMC for irradiation represent a different category of patients from those operated on at WHMC and not irradiated?

Answer: As noted in para. V of the Protocol, the research subjects are "patients with no known residual breast carcinoma". That is, by all available clinical, histological, and radiological criteria, the radical mastectomy was curative in all of these patients. It is only the referring physician's personal approach to breast carcinoma which determines that his cases receive routine post-mastectomy radiation.

It must be emphasized, however, that in this study each patient serves as his own control. That is, we are evaluating each individual patient's immune competence prior to irradiation and comparing this to what it is after irradiation. The reason for studying the nonirradiated patients (WHMC patients) is to provide additional controls. With these controls we can rule out the possibility, however unlikely, that a spontaneous decrease in immune competence regularly occurs in post-mastectomy patients at this exact time.

Para. 2.b. (SGPAR ltr): Should an equivalent number of patients and controls be used?

Answer: As noted above, each patient serves as his own control.

Finally, it must be emphasized that the purpose of this study is to determine if local irradiation results in general immuno-suppression in these patients. We are not attempting at this time to correlate the results with prognosis although this will be an obvious extension of this study if it proves to be positive.

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