

DEPARTMENT OF THE AIR FORCE
DAVID GRANT USAF MEDICAL CENTER (MAC)
TRAVIS AIR FORCE BASE, CALIFORNIA 94339

0386
575



HQIR-R

16 October 1974

Clinical Investigation of Gallium 67

AIR1.941130.062j

HQ USAF (SGPR)
Washington, D.C. 20314

Attached is a research proposal for use of Gallium 67 in a clinical investigation. Request that you review and approve this investigation and forward it to the USAF Radioisotope Committee for an amendment to our Air Force permit.

A handwritten signature in cursive script, appearing to read "Monte B. Miller".

MONTB B. MILLER, Colonel, USAF, MC
Deputy Commander

1 Atch
Proposal for Use of ^{67}Ga

Cy to: MAC/RC
HQ AMD/RD

0386
575

PROPOSAL FOR CLINICAL INVESTIGATION
Tumor Localisation Using Gallium 67

1. Purpose of Investigation: With the variety of cancer patients being referred to David Grant USAF Medical Center and the growing number of treatment protocols being evaluated under the auspices of the Western Cancer Chemotherapy Group, it has become desirable to use a tumor seeking radionuclide to better demonstrate disease in these patients. Although possessing some disadvantages, ^{67}Ga as the citrate has been used with some success. This study will attempt to evaluate the role of ^{67}Ga in decision making as to (1) the extent of cancer in patients and the effectiveness of different chemotherapy agents, and (2) demonstration of infection and abscess formations.

2. Bibliography:

a. Clouter, R. J. et al, Radiation doses from isotopes of gallium, J. Nuclear Medicine, 12 #6 (1971) 248.

b. Vaidya, B. A. et al, Localisation of Gallium 67 in malignant neoplasm. Lancet (1970) 2:911-914.

c. Edwards, G. L. et al, Tumor scanning with Gallium 67 citrate. J. Nuclear Medicine (1969) 10:103.

3. Technical Approach: It is proposed that ^{67}Ga be given to 100 patients with proven or suspected malignancy and then total body image be obtained to verify presence or absence of primary and/or metastatic disease and abscess formation. Each patient would be given up to 4 mCi of Gallium 67 as the citrate via a slow intravenous injection and images obtained 48 to 72 hours later. Correlation would be made between the scan, x-rays and other localising methods currently in use namely x-rays, angiography and routine scans using other radionuclides.

The ^{67}Ga decays with a half life of 78 hours and yields a gamma ray of 93 KEV, 184 KEV, 296 KEV and 388 KEV. Whole body dose calculated by Cloutier is 270 millirads, mCi. The bone marrow dose is 1600 millirads/mCi and for this reason no more than 4 mCi would be given to any one patient at one time.

4. Equipment: The research protocol would be carried out as part of the routine nuclear medicine laboratory procedure and no additional equipment would be required.

5. Investigation Schedule:

a. Start 1 Sep 1974.

b. Duration 2 years.

c. Summary at end of study.

d. 31 August 1976

6. Experimental Subjects: The provisions of AFR 169-8 will be complied with during this study.

7. Use of Investigational Drugs: The ⁶⁷Ca would be purchased from a licensed commercial supplier. ⁶⁷Ca has been used extensively for the past five years in humans and is now in Phase III stage of NDA with the FDA.

8. Personnel Data:

a. Medical Facility Commander: Evan W. Schear, Brigadier General, USAF, MC Commander, Medical Center

b. Neil D. Martin, Colonel, USAF, MC Chief, Radioisotope Service

9. Manpower:

- 1 Colonel, 9386N, 200 hours.
- 1 TSgt, 90470, 200 hours.
- 1 GS-4 Secretary, 70250, 4 hours.