

FROM: SGHRI

SUBJECT: Use of Na-iodide- $I^{123}$

AIR 1.941130.058g

TO: SCS

1. TITLE: Use of sodium iodide  $I^{123}$  to perform radioiodine uptake and scan.

2. PURPOSE AND BACKGROUND: Since the early 1940's the uptake of radioactive iodine by the thyroid gland has been a valuable test of metabolic status. The thyroid scan has provided invaluable information concerning topographic function. These studies have been performed in the main by iodine-131. This radionuclide, in addition to its diagnostic gamma ray, emits a rather high energy locally absorbed beta particle 90 percent of the time. This beta particle is the principle contributor to the rather high thyroid and total body radiation dose received from  $I^{131}$ . In addition, its relative long physical half-life (8 days) is another factor contributing to the radiation dose.

Recently an accelerator-produced isotope of iodine,  $I^{123}$ , has become commercially available. This isotope is a pure gamma emitter and has a 13 hour half-life. The radiation dose to the patient is approximately one-thirtieth the dose with a comparable study by iodine-131. We, therefore, propose to substitute this radionuclide for the classic iodine-131.

Biochemically, stable iodine (127) and radioactive I-131 and I-123 behave identically in the body. Unfortunately, the Food and Drug Administration regards  $I^{123}$  as a new pharmaceutical and requires that its use be administered in the same fashion as any new pharmaceutical placed on the commercial market. Thus, it is necessary to file an appropriate FDA form 1573 with the sponsoring radiopharmaceutical house. FDA regulations stipulate that any pharmaceutical filed under form 1573 have the approval of the medical facility committee on human experimentation.

We do not regard this use of radioactive iodine in any way as constituting clinical experimentation or clinical research. We are simply complying with a historically unfortunate quirk of law.

3. TECHNICAL APPROACH: Patients referred for evaluation of thyroid status will be given 100-400 microcuries of sodium iodide- $I^{123}$  by mouth, this material procured from a commercially approved source. Uptakes and scans will be performed at variable intervals. No pregnant women will be studied. The radiation dose to the thyroid is estimated at 0.1 rad and to the whole body at 0.1 mR per 100 uCi  $I^{123}$ . This dose is some 30 times less than that with  $I^{131}$ .

4. EQUIPMENT: All equipment and personnel are on hand. No special fund citations are solicited.  $I^{123}$  will be purchased through the normal operating budget of this service.

5. Investigative Schedule: This use of  $I^{123}$  is, again, not a research or experimental proposal. It will be ongoing indefinitely. A newer, better radionuclide is replacing an older, classical radionuclide. We do not expect to publish medical reports simply from the use of this agent. We, therefore, request that the usual semiannual report requirement be waived inasmuch as this application is a legal formality and not an experimental protocol.

6. Experimental Subject: No pregnant women will be studied.

7. Use of Drugs: N/A

8. Personnel data:

a. Medical Center Commander: Paul W. Myers, Brig Gen, USAF

b. Principal Investigator: William C. Harvey, Lt Col, USAF, MC

9. Manpower: Personnel allocations will not differ from those official assigned to the Nuclear Medicine Service in its normal evaluation of thyroid disease.



WILLIAM C. HARVEY, Lt Colonel, USAF, MC  
Chief, Nuclear Medicine Service