725547

BROOKHAVEN NATIONAL LABORATORY

MEMORANDUM

DATE: March 17, 1971

TO: A. Harrison

FROM: E.P. Cronkite, MD

SUBJECT: CIRC Numbers

The following CIRC #s are inactive. Except for completing old records, they should not be used for identifying patient activity until reactivation is formally approved.

Principal Investigator	CIRC #
Dr. Atkins	21
	29
	31
	43
	50
Dr. Cohn	13
	36 B
	36 D (5/22/70)

The Medical Research Center

Brookhaven National Laboratory

Upton, L. I., New York

EPC/ck

cc: Dr. Atkins
Dr. Cohn
CIRC Committee
Mr. Finn
Dr. Dahl

REPOSITORY Records Holding Area Bldg. 494

COLLECTION Committee - Clinical Investigations and uses of Radioisotopes

BOX No. 4

FOLDER CIRC #21

1179960

The Committee on Clinical Investigations and Uses of Radioisotopes hereby approves the program with the following title:

DETECTION OF BONE LESIONS WITH 87m STRONTIUM

CIRC # 21 has been assigned to this program.

Walton W. Shreeve, M.D., Ph.D., Chairman

Eugene P. Cronkite, M.D.

~~Eckart Schackow, M.D.~~ Lewis M. Schiffer, M.D.

Melvin H. Van Woert, M.D.

James S. Robertson, M.D., Ph.D. (ex officio)

Date June 7, 1965

Place Medical Research Center
Brookhaven National Laboratory
Upton, New York

1179961

Initial Approval
VB
V.P. Bond, M.D.
Chairman
MAY 28 1965

FORM FOR INITIATION OR REVIEW OF CLINICAL

INVESTIGATIVE PROGRAMS

(Submit original only to Department Chairman)

A. Title of the proposal: Detection of bone lesions with 87m strontium.

B. Sponsoring physician(s): J.S. Robertson

C. Responsible investigator(s): H.L. Atkins

D. Brief description of the study, including its general goals and purpose, and pertinent information on past studies: (Attach additional sheets if necessary.)

87m Sr can replace 85 Sr for detection of bone lesions, primarily metastases by scintiscanning. Because of its very short half-life and virtual absence of β activity, large amounts of activity may be administered enhancing statistical reliability. Scans are performed 45 min to 1 hour $\overline{p}$ injection. At this time no isotope is in the bowel, but blood background may be high.

Purpose of this study is as a service to breast cancer service for localizing and following therapeutic efforts on metastases.

E. Reasons why the investigation(s) are to be performed on human subjects.

As a service function.

F. Type of patient in which the study is to be done (including approximate number of subjects, if known; special restrictions or requirements; method of obtaining consent; etc.):

No restrictions necessary except not to be done on pregnant women.

1179962

G. 1. Are drugs not in the U. S. Pharmacopoeia (USP) or the NNR being used or contemplated for use? Yes X No ____

2. Is an unusual use of a drug(s) accepted by the USP or NNR contemplated? (An example would be the use of an accepted drug in dosages far exceeding the recommended limits or for purposes distinctly different from the usual indications cited.) Yes ____ No X

3. Are any biological products to be administered that do not bear on their containers or labels notation of approval by the Biological Control Division of the National Institutes of Health? Yes ____ No X

4. Is external or internal radiation other than accepted diagnostic or therapeutic procedures to be administered? Yes ____ No X

5. Are any (other) unusual procedures being performed or proposed which in your judgment may entail a special hazard - particularly a hazard above and beyond any imposed by accepted diagnostic and therapeutic measures for that patient? Yes ____ No X

6. Are any radioisotopes to be administered to human beings? Yes X No ____

a. If yes, are the radioisotopes to be used solely within the limits of procedures, specifically described in the USP? Yes ____ No X

Describe the radioisotopic preparation(s):

b. Or are the radioisotopes to be used only in accordance with a project previously approved by the former Radioisotope Committee of this Department? Yes ____ No X

Note the project number: _____

IF ANY OF QUESTIONS 1 THROUGH 5 ARE ANSWERED AFFIRMATIVELY, a detailed analysis of the potential hazards must be appended, including pertinent bibliographic citations and other relevant information.

IF QUESTION 6 IS ANSWERED AFFIRMATIVELY, a completed supplementary form for Radioisotope Administration to Human Beings must be appended. However, this form need not be filed provided that question 6a or 6b is also answered affirmatively. A separate form must be submitted for each radioisotopic species to be administered.

Sponsoring Physician

Committee on Clinical Investigations and Uses of Radioisotopes

Approval recommended ✓ Date JUN 1 1965

Disapproval _____ Date 6/9/65

V. P. Bond

V. P. Bond, M. D.
Chairman, Medical Department

1179963

6/25/63
mlk

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Sponsoring Physician

Committee on Clinical Investigations and Uses of Radioisotopes

Approval recommended ✓ Date JUN 1 1965

~~Disapproval~~ _____ Date 6/9/65

V. P. Bond, M. D.
Chairman, Medical Department

1179964

6/25/63
mlk

SUPPLEMENTARY FORM FOR RADIOISOTOPE

ADMINISTRATION TO HUMAN BEINGS

A. Radioisotope

1. Species: (Radioisotope or labeled compound, eg. $Na^{24}Cl$ or $1\text{-}C^{14}$- glucose)
   Strontium 87m carbonate

2. Physical characteristics: (Physical half-life; decay scheme (or type, energy and relative frequency of major emissions)
   $T_{1/2}$ = 2.8 hrs; γ - 0.388 Mev; β - none; I.C. 22%

3. Source: (BNL reactor, cyclotron, hot lab.), commercial supplier, etc.)
   Cyclotron → hot lab → Y^{87} generator

4. Preparation: (Target material, quantity, special problems)
   By hot lab.

5. Specific activity and isotopic purity of administered material:
   Spec. act. = 100% Contamination < 10^{-3}%

6. Radioassay and calibration procedures: (Include validation to be performed at BNL prior to use) Performed at hot lab. Material obtained by initial "milking" of generators before they are shipped elsewhere.

7. Vehicle and route of administration:
   Vehicle - isotonic saline. Given I.V.

8. Procedures for control of sterility and pyrogenicity: (Or note that commercially supplied isotopes are certified as ready for administration to human beings.) Obtained by milking with sterile pyrogen free solutions and passed through millipore filter. Material autoclaved prior to use.

9. Extraneous effects, if pertinent: (Such as pharmacological or toxic actions of the parent compound or vehicle, etc.) None

B. Radiation Dosage

1. Biological half-life or half-lives, including slow components:
   Biological half-life many times physical half-life.

2. Organ, cellular, or subcellular localization: (Should account for the effects of special drugs or agents on altering the natural distribution of the radioisotope)
   a. Critical or "target" organ(s): Bone .0022 rads/100 μc
   b. Gonadal exposure: Whole-body dose 0.0099 rads/100 μc

1179965

3. Sample calculations: (Dosage should be calculated for the whole body and for "target" or other separate organs, where indicated) Summary equations are desired; not extensive calculations. Standard dosage equations from references such as Hine and Brownell's Radiation Dosimetry, National Bureau of Standards Handbook 69, and BNL Hospital Form 1167-A should be used where possible and the reference cited.

Calculations taken from ref. 1.

Assumptions: (a) 100% retention
(b) Geometry factor (g) - 41.6 (Cylinder radius 5 cm, volume 7000 cc)

Usual administration will be 1 mc.

Ref. 1. Charkes, N. D. et al. Detection of metastatic cancer to bone by scintiscanning with strontium 87m. Am. J. Roent. 91, 1121, 1964.

2. Meckelnberg, R. L. Clinical value of generator produced 87-M strontium. J. Nucl. Med. 5, 929, 1964.

C. Radiological Health Aspects

1. Hazards to other patients and to personnel from external or internal radiation: No significant hazard.

2. Monitoring procedures, if necessary: -

3. Special procedures for handling waste products, excreta, biological samples, etc., where indicated: -

4. Plan for isotope accountability, if required: -

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