REFERENCES


33. Ssekasanvu E: Mycobacteria in clinical specimens of sputum smear negative adult pulmonary tuberculosis in Mulago Hospital (M.MED. Dissertation).


APPENDIX 1:

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY TITLE: A COMPARISON OF SODIUMHYPOCHLORITE, N-ACETYL-L-CYSTEIN SPUTUM CONCENTRATION METHODS AND CULTURE FOR DIAGNOSIS OF SMEAR NEGATIVE PULMONARY TUBERCULOSIS SUSPECTS IN MULAGO HOSPITAL.

Date..................  Study No..........  IP/OP No.............

Dr Omale William of Department of Medicine Makerere University is carrying out a study to determine the value of concentrating the sputum using sodium hypochlorite (Bleach). The current method of examination of sputum does not detect the germs that cause Tuberculosis in all the patients that actually have Tuberculosis. Getting a proper diagnosis of Tuberculosis will help treat the patient correctly and prevent health workers from giving treatment blindly without confirmation. The concentration method will involve getting sputum, digesting it with sodium hypochlorite and then concentrating the germs in it using a centrifuge. All that will be done by the subject will be to provide sputum samples for the procedure.

The purpose of the study

The study is conducted to discover the ability of the sputum concentration method to detect Tuberculosis germs in patients whose sputum is declared negative by the routine sputum examination method. Thus many more patients who present with symptoms (complains) like that of Tuberculosis and actually have TB may be detected and treated.

The procedure

If I agree to participate:

1. I will be asked questions about my medical history
2. I will undergo a complete medical examination.
3. I shall provide three spontaneous sputum samples for routine tests.
4. I shall provide three spontaneous sputum samples (two on the spot and one early morning) for examination to look for Tuberculosis germs. If all the 3 samples turn negative, the morning and 3rd samples out of the 3 samples above will be taken for sodium hypochlorite concentration and culture.

Risks/Discomforts

The procedure above may involve the following risks/discomforts.

1. Loss of privacy during the process of getting a history of my illness.

2. Loss of privacy during the medical examination.

The records of the study will the handled as confidentially as possible. These will be coded and kept in locked files accessible only to the investigator. Identities of individual participants will not be used in any Reports or Publication.

I will not be paid directly for participating in this study.

Benefits

Benefits of participating in this study include detection of Tuberculosis germs that will guide my treatment.

Rights to refuse or withdraw

My participation in this study is entirely voluntary, I may refuse to participate or withdraw from the study without being denied medical care. The above information has been explained and my questions answered by____________________the investigator or Research assistant.
Consent:

I have voluntarily accepted to participate as a study subject in the above study as evidenced by my signature or thumbprint below.

______________________________ _______________________________
Date Name and Signature/Thumb print of Participant
(Or legally responsible relative)

______________________________ _______________________________
Date Name of person obtaining consent.
APPENDIX 2:

QUESTIONNAIRE FOR: A STUDY OF THE COMPARISON OF THE SODIUM HYPOCHLORITE AND N-ACETYLY-L-CYSTEIN SPUTUM CONCENTRATION METHODS WITH LJ CULTURE FOR DIAGNOSIS OF INITIALLY AAFB SMEAR NEGATIVE PULMONARY TB SUSPECTS IN MULAGO HOSPITAL.

Date................. Study No.......... IP/OP No..........

A. PATIENT IDENTIFICATION

1. Name.........................

2. Age.............years.

3. Sex
   1. Male
   2. Female

4. Occupation .................

5. Marital status
   1. Single
   2. Married
   3. Divorced
   4. Widowed

6. Religion ......................

7. Address ......................

8. Date of admission ..............

9. Contact; Name ..............

   Relationship ......................

   Telephone/address ..............

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B. HISTORY OF ILLNESS

10. How long have you been coughing?

- 3 weeks = 1
- 1 month = 2
- > 1 month = 3

11. What is the colour of your sputum?

- Purulent = 1
- Whitish = 2
- Blood stained = 3
- Other = 4

12. Have you ever-coughed blood during this illness?

- Yes = 1
- No = 2

13. Do you have difficulty in breathing? Yes = 1

- No = 2

14. Do you have chest pain?

- Yes = 1
- No = 2

15. Have you been having fever?

- Yes = 1
- No = 2

16. How long have you had fever.................weeks?

17. Do you have drenching night sweats? Yes = 1

- No = 2

18. Have you had poor appetite?

- Yes = 1
- No = 2

19. Have you lost weight during this illness? Yes = 1

- No = 2
20. Have you attended to or stayed close to a person found to be having TB? [ ]
   Yes = 1
   No = 2

21. Have you ever been treated for TB before? Yes = 1 [ ]
    No = 2

22. Have you ever tested for HIV? Yes = 1 [ ]
    No = 2
    If yes, what was the result?
    Positive = 1 [ ]
    Negative = 2

23. If HIV status known, where was test done? Government health unit = 1 [ ]
    Private health unit = 2

C. CLINICAL EXAMINATION

General

24. Temperature.............centigrade.

25. Pallor (anaemia) Yes = 1 [ ]
                        No = 2

26. Wasting
    None = 1 [ ]
    Wasted = 2

27. Enlarged lymph nodes Yes = 1 [ ]
                           No = 2
    If yes, site of lymph nodes
    Cervical = 1 [ ]
    Axillary’s = 2
    Cervical and axillary = 3
    Generalised = 4
28. Herpes zoster scar

Yes = 1

No = 2

39. Kaposis sarcoma lesion

Yes = 1

No = 2

30. Oral thrash

Yes = 1

No = 2

31. Finger clubbing

Yes = 1

No = 2

Respiratory Examination

32. Respiratory rate

33. Chest findings

Yes = 1

No = 2

If yes, specify

1. Abnormal sounds (crackles, bronchial breathing, ronchi)

2. Pleural effusion

3. Consolidation

Abdominal examination

34. Liver

Palpable = 1

Not palpable = 2

35. Spleen

Palpable = 1

Not palpable = 2
D. LABORATORY REPORTS

Sputum

36. Direct sputum smear: 1\textsuperscript{st} ............... 2\textsuperscript{nd} ................. 3\textsuperscript{rd} ......................

  Sodium hypochlorite concentration: Positive = 1
  Negative = 2

37. NALC concentration:
  Positive = 1
  Negative = 2

38. Culture (LG)
  Growth present = 1
  No growth = 2
  Contaminated = 3

  If growth present, number of colonies: 1-19 colonies = 1
  20 - innumerable = 2
  Confluent growth = 3