

APPENDICES

Appendix 1 : Consent form

Cost-effectiveness of Isoniazid 9 months versus Rifampicin plus Pyrazinamide for prevention to active tuberculosis among HIV-infected persons in Chiang Rai, Thailand

TB/HIV Research project, Provincial health office Chiang Rai and TB Division,
Ministry of Public Health, Thailand

Now, .. We are asking you to take part in this research study. What this would mean to you is that today we would take another chest x-ray, sputum smear, tuberculin skin test and a tube of blood from a vein in your arm. Your blood will be tested to make sure you are the kind of person who is less likely to have side effects from the antibiotic and the medicine used to prevent TB, to see how early or advanced your HIV infection is, and to make sure you are not pregnant(in case woman). If everything from the tests looks ok for you to be part of the study , you would need to come back in two weeks, to give another blood sample and then every month after that come to this clinic to be checked and to get your medicines. “Being checked” means answering simple questions about your health, having the pills that are leftover from your last refill checked, and giving a urine sample, you will be apart of the study for 9 monthss, or until you get sick with TB, can’t take the medicine because of side effects, or because you don’t take the medicines or come for follow-up as directed.

Benefits: Those participants who may benefit from the TB chemoprophylaxis will be provided with free medication, after they are counselled about TB. Everyone in the study takes at least two months of the TB tablets which can greatly reduce the

chance that you will get TB and may have fewer infections than if they weren't in the study. You will also be seen by a nurse or doctor once a month so that if you do become sick you may be treated sooner. You should come back sooner than your scheduled appointment to get the right care. This research may also help us care for other persons living with HIV/AIDS in the future.

Risk/Discomforts: If you feel uncomfortable to answer some of the question, you have a right to skip or stop answering. Regarding to the skin tests, the antigens are widely used and well proven as safe. Well-trained personnel will carefully perform the skin tests with internationally standardized antigens to minimize the pain, ulcerations, slough and contaminated infection at the injection sites. Major inconvenience is the requirement that you have to return for two days later. We will reimburse you transportation or other expenses in connection with the participation in this study.

Taking the blood from your arm may cause mild pain from the needle and cause a slight change in color in the skin where the needle goes in.(This take a few days to normal.) Your body will replace the small amount of blood we take in a few days. Some people get side effects from the TB medicine, these side effects are usually mild and don't last long, like a little rash or stomach upset. But sometimes the side effects are serious, like liver disease. We will try to not let this happen.

Confidentiality: Your name will be used in any speech or paper about this study. We will not share any of your results with anyone or tell your status to other people like your friends, family, or boss.

Refusal to participate: If you do not want to take part in this research study you can change your mind at any time and stop being in the study . If you have any questions about your rights in this study you can talk to Dr..... and Ms. Saiyud Moolphate(Research nurse) TB/HIV research project, 1050 Sathanpayaban Road, Muang District, Chiang Rai, Thailand. Tel: 053-713135

When you sign below, it shows that you agree to let us enroll you in the study. If there is any part of the study that is not clear to you, ask the nurse or doctor about it now. Do not sign until you get answers for all your questions. If you agree to be in this study, please sign here.

I,(name) _____

Address number _____ mu _____ tambol _____ amphur _____

Province _____, have been explained and understand the information contained in this form explanation.

I understand that my participation is entirely voluntary, and that I can change the consent at any time when I wish. I voluntarily participate in the study.

Signature _____ (participant)

Signature _____ (responsible person)

Signature _____ (witness)

Date...../...../2003

Appendix 2: Enrollment Questionnaire form of treatment of LTBI

Study ID _____

Cost-effectiveness of Isoniazid 9 months versus Rifampicin plus Pyrazinamide for prevention to active tuberculosis among HIV-infected persons in Chiang Rai province, Thailand

Interviewer.....

Information Filling or marking (√) in a blank space or right answer

- 1. Date of screening (dd/mm/yyyy).....
- 2. Name.....
- 3. Hospital..... HN..... DCC No.....

Demographic characteristics

- 4. Sex male female
- 5. What is your birthdate?(dd/mm/yyyy)Age(years)

Patient must be 18 –50 to be enrolled.

- 6. Address
 - number of house name of village
 - Moo.....Sub-district

District

- | | | |
|------------------------------------|--|---|
| <input type="checkbox"/> Maung | <input type="checkbox"/> Weing Chai | <input type="checkbox"/> Chiang Khong |
| <input type="checkbox"/> Tong | <input type="checkbox"/> Phan | <input type="checkbox"/> Padad |
| <input type="checkbox"/> Mae Chan | <input type="checkbox"/> Chiang San | <input type="checkbox"/> Mae Sai |
| <input type="checkbox"/> Mae Sreoy | <input type="checkbox"/> Wiang Pa Pao | <input type="checkbox"/> Paya Meang Rai |
| <input type="checkbox"/> Wiang Kan | <input type="checkbox"/> Mae Pha Loang | <input type="checkbox"/> Kun Tan |
| <input type="checkbox"/> Mae Lao | <input type="checkbox"/> Wiang Chiang Rung | <input type="checkbox"/> Doi Luang |

7. Phone number.....

8. Citizen ID.....

9. Name of close friend or relative who will know the subject's outcome in case the subject is lost to follow-up.....

10. Nationality

- Thai Foreign (specify)

11. Ethnic

- Thai Chinese Burmese Laos
- Hill-tribe (specify).....

12. The highest educational level

- None Primary school Secondary school
- College/ Vocational training Bachelor/Post graduate
- other (specific).....

13. Occupational

- Farmer Civil servant Labor
- Merchandise Housewife student

- Military/ Police Fisherman Teacher
 Employed by company Self-employed
 Monkshood Unemployed
 Other (specify).....

14. Marital status

- Single Marriage Divorce
 Widow others

Patient cost of program

15. Do you have health insurance ?

- 30 baht 30 baht with gold card social security insurance
 Civil servant medical benefit
 Free medical care for the elderly(Elderly card) Nothing

16. Average Income..... Baht/day

17. How many days do you work per week..... Days

18. Do you pay any money to hospital for this visit?

- No Yes, how much..... baht and for what

(list)1.....

2.....

3.....

19. You go to hospital by.....

- Bus Tuk-Tuk Motorcycle
 Own car Others.....

20. How far from your house to hospital?.....Kilometers

21. How many person go to hospital with you?..... persons

22. How much you pay for transportation cost (patient) in this visit.....Baht

23. How much you pay for transportation cost(relatives) in this visit.....Baht

24. Do you have to stay overnight for this visit?

- [1] Yes [2] No

If yes, how much you pay for accommodation.....baht (patient)

If yes, how much you pay for accommodation.....baht (relatives)

25. Do you ask any body to look for your house while you go to hospital?

- [] No [] Yes

If yes, do you pay money for them for look after your house?

- [] No [] Yes.....baht

26. Do you ask any body to look for your child while you go to hospital?

- No Yes

If yes, do you pay money for them for look after your child?

- No Yes.....baht

TB screening

27. Has the subject had any of the following? (can check more than 1 choice)

- | | | |
|--|------------------------------|-----------------------------|
| 1. Chronic cough more than 2 weeks | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Coughing up blood (Hemoptysis) | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3. Fever > 2 weeks | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 4. Night sweats | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 5. Body weight decrease less than 10% (unexplained weight loss) | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 6. Shortness of breath | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 7. Chest pain | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 8. Fatigue poor appetite | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 9. Others/specify | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

28. Has the patient ever taken treatment for TB? Yes No

If yes, Where did you get the treatment and how long were your treatment result?

.....

If “yes”, patient is ineligible for study.

29. On DM treatment Yes No

30. What is patient's estimated Karnofsky status?.....

Must be \geq 60 for enrollment.

31. Is the patient taking any antiretroviral drugs now?

If yes, specific.....

32. Other than antiretrovirals, is patient taking other medications? (Do you on regular drug?)

If yes, please list.....

Side effect screening

33. Has patient ever been told he or she had viral hepatitis or any serious liver disease?

Yes No

34. Alcoholism(Drink alcohol everyday in past 6 months)

Yes No

35. Pregnancy?

Yes No

36. Has the patient ever had a serious reaction to any medication?

Yes No

If yes, which medication?.....

What was the reaction?

1. rash 2. Trouble breathing 3. Hematological reaction(anemia)
 4. swelling 5. Unsure

Adherence screening

37. Do you have plan to move to another province?(Uncertain address)

Yes

No

38. Do you allow health staff for home visit?

Yes

No

39. Have you ever used drug addict?

Yes

No

Physical examination

40. Body WeightKilograms Height..... Centimeters

41. BCG scar

Yes

No

42. Oral candidiasis or hairy leukoplakia

Yes

No

43. Herpes Zoster more than 1 dermatome

Yes

No

44. Central nervous system dysfunction

Yes

No

Laboratory

45. Chest x ray date(dd/mm/year).....

normal

abnormal specific.....

46. Sputum smear AFB date

1.(dd/mm/year)..... positive..... negative

2. (dd/mm/year)..... positive..... negative

3. (dd/mm/year)..... positive..... negative

47. CD4.....

48. CBC date obtained (dd/mm/year).....

Total

WBC.....

Neutrophil count.....

Heamoglobin.....

Platelets.....

49. Liver function test : SGOT(aspirate aminotransaminase)

(dd/mm/year).....

Total bilirubin.....

50. Creatinine(dd/mm/year).....

PPD skin test

51. Have you ever had Tuberculosis skin test before?

[1] Yes/when..... [2] No

52. D/M/Y of skin test/...../..... Time ____ . ____ am./pm.

Location of skin tests

- [] Left forearm \longrightarrow PPD test
- [] Right forearm \longrightarrow PPD test

Researcher nurse

53. Appointment date for reading (D/M/Y)/...../..... Timeam./pm.

Appointment place for reading

[1] At hospital..... [2] At home or health center.....

Reading skin test

This part should be asked when skin tests are read (2-3 days) but not later than 5 days.

54. Reading Date (D/M/Y)/...../..... Time ____ . ____ am./pm.

| |
|---|
| 55. The longest diameter of induration(not erythema) in mm |
| PPD Test = mm. |
| Reader's signature..... |

56. Does the contact case complain any side effects?

- | | | |
|---------------|---------|--------|
| 1 Erythema | [1] Yes | [2] No |
| 2 Blister | [1] Yes | [2] No |
| 3 Others..... | | |

Conclusion

This patient can meet criteria....

- [] Yes , if yes which regimen..... [] No, because.....

Appendix 3: Follow up questionnaire form

Study ID _____

Cost-effectiveness of Isoniazid 9 months versus Rifampicin plus Pyrazinamide for prevention to active tuberculosis among HIV-infected persons in Chiang Rai, Thailand

Interviewer.....

Information Filling or marking (√) in a blank space or right answer

1. Date of follow up (dd/mm/yyyy).....

2. Name.....

3. Hospital..... HN..... DCC No..... IPT No.....

Patient cost of program

4. How many days do you work per month.....Days

5. Do you pay any money to hospital for this visit?

No Yes, how much.....baht and for what

(list)

1.....

2.....

3.....

6. You go to hospital by.....

- Bus Tuk-Tuk Motorcycle
 Own car Others.....

7. How far from your house to hospital?.....Kilometers

8. How many person go to hospital with you?..... persons

9. How much you pay for transportation cost (patient) in this visit..... Baht

10. How much you pay for transportation cost(relatives) in this visit..... Baht

11. Do you have to stay overnight for this visit?

- [1] Yes [2] No

If yes, how much you pay for accommodation.....baht (patient)

If yes, how much you pay for accommodation.....baht (relatives)

12. Do you ask any body to look for your house while you go to hospital?

- [] No [] Yes

If yes, do you pay money for them for look after your house?

- [] No [] Yes.....baht

13. Do you ask any body to look for your child while you go to hospital?

- [] No [] Yes

If yes, do you pay money for them for look after your child?

No

Yes.....baht

Evaluation for active TB

14. Has subject's had any known exposure to active TB since last follow-up visit?

Yes

No

Unknown

15. Has the subject had any of following ?

15.1 Chronic cough more than 2 weeks Yes No

15.2 Coughing up blood (Hemoptysis) Yes No

15.3 Fever > 2 weeks Yes No

15.4 Night sweats Yes No

15.5 Body weight decrease less than 10% Yes No

(unexplained weight loss)

15.6 Shortness of breath Yes No

15.7 Chest pain Yes No

15.8 Fatigue poor appetite Yes No

Evaluation for compliance with study medications

16. Does the subject report taking all medications?

Yes

No

17. From INH pill count, how many missed doses have there been in the last month?

= 0-5 = 6-10 = 11-15 = 16-20 = >20 unknown

18. What are the results of INH urine metabolite test?

Negative Positiave Not done

19. What is the color of urine ?

yellow(normal) orange

Evaluation for drug side effects

20. Has the subject had any of the following symptoms that might be related medications?

- | | | | |
|---------------------------------------|------------------------------|-----------------------------|----------------------------------|
| a) Jaundice | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| b) exfoliate dermatitis | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| c) peripheral neuropathy | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| d) persistent joint pains | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| e) nausea/vomiting | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| f) abdominal pain | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| g) loose stools (3 in 24 hour period) | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| i) less frequent urination | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| j) swelling of feet | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| k) shortness of breath | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| l) paleness and/or severe fatigue | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |

Appendix IV: Work Sheets for Cost Calculation

Hospital point of view

| (1) Items | (2) Unit | (3) Formula | (4) Unit cost of the item | (5) Hour or weight or volume or test or unit used for 1 HIV infected person during 9 months | (6) Sub total cost of the item (4 X 5) |
|--------------------|----------------------|--------------------------------|------------------------------|--|---|
| Counselling | | | | | |
| Nurse | 1 hour | (1 hour *salary/(20day*8hour) | X baht / hour | X hours | (X hour) * X baht/ hour |
| PLWA volunteer | 1 hour | (1 hour *salary/(20day*8hour) | X baht / hour | X hours | (X hour) * X baht/ hour |
| | | | | | |
| Consultants | | | | | |
| Physician | 1 hour | (1 hour *salary/(20day*8hour) | X baht / hour | X hours | (X hour) * X baht/ hour |
| | | | | | |
| Medication | | | | | |
| Anti-TB drug | | | | | |
| IN H | 1 tablet (100 mg) | 1 tablet = X baht | X Baht/ 1 tablet(100 mg) | 3 tablets X 270 day = 810 tablets | X Baht/tab * 810 tablets |
| Vit B6 | 1 tablet (100 mg) | 1 tablet = X baht | X Baht/ 1 tablet(100 mg) | 1 tablets X 270 day = 270 tablets | X Baht/tab * 270 tablets |
| | | | | | |

| (1) Items | (2) Unit | (3) Formula | (4) Unit cost of the item | (5) Hour or weight or volume or test or unit used for 1 HIV infected person during 9 months | (6) Sub total cost of the item (4 X 5) |
|---------------------------------------|-----------------|--------------------------------|------------------------------|--|---|
| Treating drug from side effect of INH | | | | | |
| Consultant(Physician) | 1 hour | (1 hour *salary/(20day*8hour) | X baht / hour | X hours | (X hour) * X baht/ hour |
| Laboratory (up to side effect) | 1 test | 1 test = X baht | X baht / test | X test | (X test) * X baht / test |
| Medication (up to side effect) | 1 tablet (x mg) | 1 tablet(x mg) = X baht | X Baht/ 1 tablet(x mg) | X tablet(x mg) | X tablet(x mg) * X Baht/ 1 tablet(x mg) |
| | | | | | |
| Laboratory | | | | | |
| Sputum microscope | 1 slide | 1 slide = X baht | X baht / slide | 3 slides * 2 times = 6 slides | (X baht) / slide * 6 slides |
| Sputum culture | 1 specimen | 1 specimen = X baht | X baht / specimen | 1 specimen | (X baht) / specimen |
| HIV | 1 test | 1 test = X baht | X baht / test | 1 test | X baht / test |
| SGOT | 1 test | 1 test = X baht | X baht / test | X tests | (X tests) * X baht / test |
| Bilirubine | 1 test | 1 test = X baht | X baht / test | X tests | (X tests) * X baht / test |
| Tuberculin Skin Test (TST) | 1 test | 1 test = X baht | X baht / test | 1 test | X baht / test |
| | | | | | |
| | | | | | |
| | | | | | |

| (1) Items | (2) Unit | (3) Formula | (4) Unit cost of the item | (5) Hour or weight or volume or test or unit used for 1 HIV infected person during 9 months | (6) Sub total cost of the item (4 X 5) |
|--|-------------|--|------------------------------|--|---|
| Managing for patient loss follow up | | | | | |
| Nurse | 1 hour | (1 hour *salary/(20day*8hour) | X baht / hour | X hours | (X hour) * X baht/ hour |
| Driver | 1 hour | (1 hour *salary/(20day*8hour) | X baht / hour | X hours | (X hour) * X baht/ hour |
| Vehicle's operation & maintenance | 1 day | Fuel+ lubricans+ batteries, insurance+registertion fees,etc. in 1 year <hr/> 365 days | X baht / day | X day | (X day) * X baht / day |
| Total cost for 1 HIV infected person of INH regimen | | | | | $\sum x$ |
| Average cost of HIV infected person of INH regimen in program = $\frac{\sum x_1 + \sum x_2 + \sum x_3 + \sum x_4 + \dots + \sum x_n}{N}$ | | | | | |
| N= number of patient in program | | | | | |



CURRICULUM VITAE

Name Saiyud Moolphate

Gender Female

Date of birth January 31, 1969

Place of Birth Chiang Khong, Chiang Rai, Thailand

Marital status Single

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Education and Training

June, 2000 Introductory Course on Field Epidemiology,
International Field Epidemiology Training Program
(FETP), Ministry of Public Health Thailand.

March 1992 Bachelor of Nursing Science, Faculty of Nursing,
Chiang Mai University, Chiang Mai, Thailand G.P.A.

March 1988 High School, Samakkee Vittayakhom School,
Chiang Rai, Thailand G.P.A. 3.6

Professional Experiences

August 1998-present Research Coordinator,
TB/HIV Research Project-Thailand,
An international collaborative research project under the
control of the Research Institute of Tuberculosis (RIT),
Japan and the Ministry of Public Health, Thailand.
(Coordinating research activities. The design,
implementation, analysis and writing of the research are
integral to this position, under the supervision of
Dr.Hideki Yanai and Dr.Pathom Sawanpanyalert)

March 1998-July 1998 Pattaya International Hospital, Pattaya city,
Chonburi, Thailand
(Staff nurse in the In-Patient Department: medical,
surgical, pediatric and obstetric and gynecological)

April,1997-Feb 1998 Becton&Dickenson Co.Ltd., Thailand
(Medical sale representative in northern provinces,
Thailand. Experienced in hospital purchasing policy on
pharmaceutical products, purchasing behaviours of the

hospitals and health care professionals, pharmaceutical product marketing, negotiation skills, lobbying)

April,1993 –Mar 1997

Bangkok General Hospital, Bangkok,Thailand

(Staff nurse in cardiac care unit at the private Hospital in part of Bangkok Heart institute of Bangkok General Hospital. Skills and experiences included caring for patients with conditions such as myocardial infarction, congestive heart failure, thrombolytic therapy, temporary and percutaneous transluminal angioplasty, automatic implantable cardioverter-defibrillator, and also caring for the patient who underwent open and closed heart surgery such as coronary artery bypass graft(CABG), valvulotomy, closure of septal defects and vascular surgery.)

Mar,1992 - Mar ,1993

Phattaravej Hospital, Pichit, Thailand

(Pioneer staff nurse in the intensive care unit at the major hospital in Pichit. Responsibility included developing the services and administrative system. Experiences included neurological and neurosurgical care.)

References

Hideki Yanai, MD, Dr.PH, Project Manager, TB/HIV Research Project (Thailand-Japan collaboration)

The Research Institute of Tuberculosis, JATA, Tokyo,
Japan.

Surachai Piyaworawong,MD

Mae Chan Hospital,Chiang Rai, Thailand.

Publications and Presentations

Likitpongton K, Sawanpanyalert P, Moolphate S, Saksoong P, Piyaworawong S, Yanai H. Risk Factors for Hepatitis C Virus Infection Among Drug Users in Northern Thailand. Bulletin of the Department of Medical Sciences, Thailand.2000; in press

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Saksoong P, Sawanpanyalert P, Piyawonrawong S, Moolphate S, Akarasewi P, Supawitkul S, Yanai H. Setting up Cohort Follow-up System for Drug Users: A Need for Health Care Strengthening. 5th Congress on AIDs in Asia and the Pacific, Kalalumpur, October 22-26, 1999(Oral Abstract 612/TCD12-05)