

References

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Appendix A

Data Collection Form

| Code for fill-in blanks: 9 = missing, unknown or not performed, 8 = can't | t evaluate |
|---|----------------------|
| Baseline data: Code No Name Hospital No | |
| Code No Name Hospital No | 1 00 |
| 2. Hospital No | 1. [] [] 2. [] [] |
| 3. Age (years) | 3. [][] |
| 4. Sex [] 1. M, [] 2. F | 4. [][] |
| 5. Duration of sickness (days) | |
| 6. FAB subtypes []1.M1, []2.M2, []3.M3, | 5. [] [] [] 6. [] |
| 7 | 6. [] |
| [] 4.M4, [] 5.M5, [] 6. M6 | 7 (1) |
| 7. Performance status []0, []1, []2, []3, []4 | 7. [] |
| 8. Hemoglobin (g/L) | 8. [] [] [] |
| 9. WBC (X10 ⁹ /L) | 9. [][][].[][] |
| 10. Platelets (X10 ⁹ /L) | 10. [] [] [] [] |
| 11. Severe bone marrow suppression period (days) | 11. [] [] |
| 12. Bone marrow recovery period (days) | 12. [] [] |
| 13. Stratification: []1.Newly diagnosed, []2.Relapsed, []3.Consolidation | 13. [] |
| 14. Complete remission after induction []1. Yes, []2. No | 14. [] |
| <u>Outcomes</u> | |
| Primary | 16 17 |
| 15. []1. Infection, []2. Non-infection | 15. [] |
| Secondary | 16.53 |
| 16. Death []1. Yes, []2. No | 16. [] |
| 17. Causes of death []1. Infection, []2. Bleeding, []3. Others | 17. [] |
| 18. Total days of fever | 18. [] [] |
| 19. Total days of antibiotics given | 19. [] [] |
| 20. Types of antibiotics | 20. [] |
| []1. Aminoglycoside+anti-pseudomonal penicillin | |
| []2. Aminoglycoside+3rd generation cephalosporin | |
| []3. Aminoglycoside+imipenem/cilastatin | |
| []4. 3rd generation cephalosporine or imipenem/cilastatin alone | 9.7 |
| 21. Numbers of antibiotic modification | 21. [] [] |
| 22. Addition of antifungal drugs []1. Yes, []2. No | 22. [] |
| 23. Categories of infection | 23. [] |
| [] . Bacteremia, []2. Other bacterially documented | |
| []3. Clinically documented, []4. Unexplained fever | |
| 24. Nausea []1. Yes, []2. No | 24. [] |
| 25. Vomiting | 25. [] [] |
| 26. Platelet transfusions (units) | 26. [] [] |
| 27. Packed red blood cell transfusions (units) | 27. [] [] |
| 28. No. of positive fungal cultures: Rectum Oropharynx | |
| 29. Kind of fungi | |

Appendix B

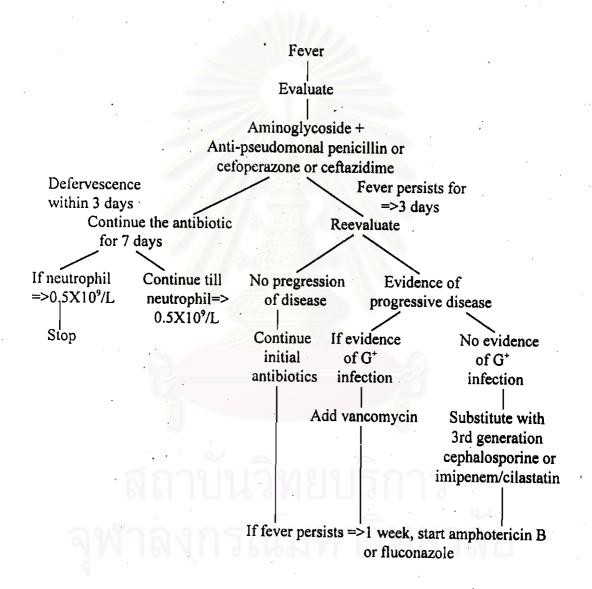
ECOG Criteria for Estimation of Performance Status

Grade Scales

- 0 Fully active, able to carry on pre-disease performance without restriction
- 1 Ambulatory, but have symptoms
- 2 Ambulatory, confined to bed and chair less than 50% of waking hours
- 3 Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 Completely disabled, can't carry on any self-care, totally confined to bed or chair

Appendix C

Antibiotic Guidelines



Appendix D

CONSENT FORM

I have been informed that the Department of Hematology, First General Hospital of West China University of Medical Sciences is conducting a study on the prevention of infections of acute myelogenous leukemia patients. The purpose of this study is to evaluate whether oral ingestion of medical plant can prevent the patients from getting infected during this course of chemotherapy.

I agree to participate in this study and understand it will involve the following procedure:

- 1. General physical examination every day and whenever necessary.
- 2. Bacterial surveillance cultures once a week.
- 3. Proposed treatment for 28 days or shorter if my peripheral white blood cell count exceeds 2X10⁹/L within 28 days.
- 4. Routine treatment for acute myelogenous leukemia and other related conditions.

I am informed that the medicine I will be taking may work or may not work for the purpose of infection prophylaxis. I am also informed of the possible side effect of the medicine.

I understand that if I do not participate in the study, I will have the alternative of routine treatment for my disease.

I understand that my agreement of participation in this study is entirely voluntary and I may withdraw at any time without having to give any reason. The quality of my medical care will not be influenced by my refusal or withdrawal from the study.

My attending physician has already talked with me about the study and answered all my questions related to the study. I have been informed that I have the opportunity to ask more questions about this study and I can also contact the researchers in this hospital on Tel. ext. 23589.

| Patient's name: | | | Date of | | |
|---------------------|--|--|---------|--|--|
| | | | | | |
| Physician's name: _ | | | · | | |



VITAE

Dr. Li Qin was born on January 15, 1963 in Xinjiang, P. R. China. She graduated from the School of Medicine, West China University of Medical Sciences, Chengdu, in 1986 after accomplishment of a six-year course and obtained an M.D.

After graduation, she completed 2 years of residency of general internal medicine in the Department of Internal Medicine, First General Hospital of West China University of Medical Sciences. Then she was enrolled in postgraduate study and obtained a master degree in hematology in 1991. After that she completed 2 years of fellowship and 1 year chief residency in the Department of Hematology, First General Hospital of West China University of Medical Sciences. She has been working as an attending physician of hematology since 1994. Since June, 1996, she has been admitted in the Master Degree Program of Health Development in Faculty of Medicine of Chulalongkorn University, Bangkok, Thailand. She was supported in this program by Thai CERTC (Clinical Epidemiology Regional Training Center) consortium of INCLEN (International Clinical Epidemiology Network), principally sponsored by Rockefeller Foundation, New York, USA.

Her principal interest in the medical field is research in hematology, especially in the infection of immuno-compromised patients. During this course, she has conducted a clinical controlled trial on the efficacy of garlic, a natural plant, on the prevention of infection of acute myelogenous leukemia patients during chemotherapy.

Presently, she is working as an attending physician in the Department of Hematology, First General Hospital of West China University of Medical Sciences. Her interest and the training she received in the field of clinical epidemiology also enable her to teach clinical epidemiology in the CEU of West China University of Medical Sciences, Chengdu.