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＜その他＞

1. PBSC の細胞濃度、添加する抗凝固剤や自己血漿の割合、オーバーナイトで保存する時と運搬時の温度についてのガイドライン

・ オーバーナイトで保存するときも、運搬時も 2～8℃とする。
・ 採取した PBSC の総量は、最低 200ml。血球分離器によっては自己血漿を採取し、採取した PBSC へ添加する必要があるものがある。単核細胞採取での一般的なクエン酸:全血の割合は 1:12～1:13 である。
・ この割合においては、ACD-A:最終的なプロダクト中の血漿の割合は 1:6～1:8 がよい。
・ 細胞濃度についての記載はない。

○PBSC プロトコールより原文引用

11.4.1. Leukapheresis schedule

One or two mononuclear cell-leukapheresis collections will be required and determined according to the unadjusted body weight of the recipient (Table 3). PBSC will be collected using the Fenwal CS-3000, COBE Spectra or comparable automated cell separator according to established procedures. The apheresis facility must have a written procedure(s) for the collection of peripheral blood stem cells by leukapheresis.

It is expected that routine leukapheresis procedures under this protocol will only occur on Monday through Friday. The available schedules for leukapheresis are displayed in Table 4 for all recipient weights.

Each PBSC product, each day of collection, should have a minimum final volume of 200 mL after removal of a maximum of 5 mL for testing. For some blood cell separators, additional autologous plasma will need to be collected and added to the PBSC product at the end of the procedure. Mononuclear cell apheresis collections are generally performed using citrate:whole blood ratios of 1:12 to 1:13. Using these ratios, the ACD-A:plasma ratio in the final product should be 1:6 to 1:8.

The use of heparin to reduce ACD-A requirements during leukapheresis is allowed, but at low ratios there is an increased rate of clotting in the product. Therefore, if a citrate:whole blood ratio of less than 1:13 is used, then 15 mL of ACD-A should be added to the component bag immediately after the procedure is completed to prevent the product from clotting.

1. ドナーのフォローアップについて(資料 8)

・ プロトコルに則ってドナーセンターの責任下で行っている。
・ ドナーセンターがドナーに健康状態を伺い(電話・メール等にて)、NMDPの指定するフォームを提出する。具体的な方法はBMもPBSCも同様で、以下のとおりである。

○採取2日後、1週間後(その後はドナーが回復するまで週1回) : ドナーの健康状態をチェックするアンケートを行う。(資料 9)
○1ヵ月後、6ヵ月後 : データ収集のために健康状態を伺い、NMDPが指定するフォームを提出する。
○その後1年に1回、ドナーが必要とする限り一生 : NMDPの長期フォローアップの一環としてドナーの健康状態を確認する。(資料 10)
※血液検査を特定の時期に実施することを決めてはいないが、ドナーが参加している研究があればそのプロトコルに従って実施する。

【資料 8 】

11. Post Donation Follow-Up

Purpose

To provide post donation follow-up requirements for data collection and confidentiality.

Tools and Resources

- Donor Forms Instruction Manual
- FormsNet™ application
- FormsNet™ User's Guide
- NMDP Network Web Site
- NMDP Standards
- PBSC Resource Manual
- PBSC vs. Marrow Randomized Trial Donor Companion Manual
- STAR Link® application
- STAR Link® User's Guide
- Webmail
- Webmail User's Guide
- Webscripts
- Webscripts: Donor Center User Guide

Materials

- CIBMTR / NMDP Protocol Deviation Form 3000 ..... Network Web site
- Consent to Release a Donor's Personal Information ..... Network Web site
- Consent to Release a Recipient's Personal Information ..... Network Web site/TC generated
- Donor Center Manual of Operations: Adverse Events Chapter ..... Network Web site
- Form 180 Series ..... Network Web site/TC generated
- Form 701 ..... Network Web site
- Form 760 ..... Network Web site
- Form 777 ..... Network Web site
- Form 778 ..... Network Web site
- Form 779 ..... Network Web site
- NMDP Donor & Patient Confidentiality Guidelines ..... Network Web site
- NMDP International Centers Policies Regarding Post-Transplant Communication Between Donor and Recipient ..... Network Web site
- Procedure to Obtain Consent to Release Donor Information ..... Network Web site
- Procedure to Obtain Consent to Release Patient Information ..... Network Web site

Table of Contents

11.1. Overview

After a stem cell collection, the donor's health must be assessed to monitor the recovery process and long-term health effects of the donation, as well as to ensure that the donor continues to observe confidentiality requirements.

11.2. Software Applications and Processes

NMDP Network donor centers communicate with the NMDP using an approved process or application. In this chapter, the reader will find references to donor centers receiving or entering information in the STAR Link application. Donor centers that do not use the STAR Link application should receive and must enter the equivalent information using Webscripts or another NMDP-approved application. See the *STAR Link User's Guide* or *Webscripts: Donor Center User Guide* for additional information.

11.3. Forms Submission

Data Collection Forms (DCF) refers to the collection of required data for data entry and storage in the STAR® system. DCFs include the Form 700 series, Form 24 and Form 50. In this chapter, when donor centers are instructed to submit a form to the NMDP or Search Coordinating Unit (SCU), the donor center is responsible for submitting the form in the appropriate manner. This may include submitting forms via the FormsNet™ application, fax, or mail.

Infectious Disease Marker (IDM) information is used to determine eligibility of donors to donate their stem cells according to FDA regulatory requirements. Donor center staff are responsible for obtaining IDM testing and screening results from the testing laboratory and for accurately reporting the results to the NMDP on the Forms 24 and 50. The reporting process should include at least a two-step review process to ensure accuracy.

Additionally, there are forms that donor centers complete or receive that are not entered into the STAR system, for example, product verifications, health history forms, etc. The donor center submits these types of forms as requested via fax, mail or other acceptable process.

It is the responsibility of the donor center to submit required forms to the NMDP. The NMDP has a tracking system in place to assist donor centers in identifying when a form is due and if it has been received and entered at the NMDP. When a form becomes due, or is past due, it appears on a center specific forms due report. For additional information on forms submission, see the *FormsNet User's Guide* and *Donor Forms Instruction Manual*.

11.4. Donor Deferral Recommendations

After a donor provides a stem cell or blood product, there are required time frames during which the donor is not "available" for other potential recipients. The time frames will vary depending on if it is the donor's first or second donation, but the following guidelines apply to most situations:

- After a first stem cell donation (marrow or PBSC) the donor is TU for one year.
- After a second stem cell donation the donor is TU for three years.

These recommendations do not apply to situations where a donor is asked to make a subsequent donation to the same recipient. When the same recipient needs a donation from the same donor the waiting periods are reduced to two - four weeks. See *Policy for Subsequent Donation by NMDP Donors.*

11.5. Follow-Up Schedule

After a marrow or peripheral blood stem cell (PBSC) collection, the donor center is responsible for evaluating the donor's health at specific time intervals as defined in specific NMDP clinical trial protocols and the *NMDP Standards.* The *Donor Forms Instruction Manual* provides information on collecting data and completing the NMDP 700 series data collection forms (DCFs).

Donor follow-up after marrow or PBSC donation is required within 48 hours of donation, at one week, weekly until the donor reports full recovery, at one month, six months and annually. When the donor reaches 61 years of age and is deleted from the NMDP Registry, annual follow-up is still required. Follow-up time points and whether blood tests are required differ depending upon trial-specific protocol requirements. The "forms due" function in the STAR Link application identifies when each DCF (form) is due.

In the event the donor receives a homologous (not the donor's own) blood product, there is a delay in discharging the donor from the hospital, or an adverse event occurs, the donor center must immediately notify the NMDP Search Coordinating Unit (SCU). See the *Adverse Events* chapter in this manual for additional information.

11.5.1. Immediate Donor Follow-Up

Donor follow-up is required within 48 hours post donation. The donor center is responsible for the following activities:

A. Contact a member of the collection team to be aware of any problems or complications that occurred during the stem cell collection.

B. Contact the donor.

C. Document each donor follow-up encounter by completing the Form 777, *Stem Cell Donor Follow-Up Evaluation.*

D. Submit the form to the NMDP and maintain a copy in the donor chart.

E. Call the SCU immediately if the donor reports any adverse events that are grade 3 or higher and then report on the Form 701, *Stem Cell Donor Adverse Event Form.*

F. If the donor reports any adverse events that are grade 2 or less, the Form 701 does not need to be completed.

11.5.2. Weekly Donor Follow-Up

Donor follow-up is required at one week post-donation and then weekly until the donor reports full recovery. In some circumstances, the donor follow-up may be more or less frequent than at one-week intervals.

The donor center is responsible for the following activities:

A. Contact the stem cell donor within one-week post-donation and then at seven-day intervals until all responses to the donor health assessment questions indicate complete recovery.

B. Document each donor follow-up encounter by completing a Form 777. The one-week is completed on a Form 780 and ongoing weekly follow-up is completed on a Form 781.

C. Submit the form to the NMDP and maintain the original in the donor chart.

11.5.3. Ongoing Follow-Up

Donor follow-up is required at one month, six months and annually post donation. The donor center is responsible for the following activities:

A. Contact the stem cell donor at the specified time intervals.

B. Arrange for the blood work for the annual follow-up according to the specific protocol.

   1. PBSC vs. Marrow Randomized Trial donors require an annual CBC for three years after collection.

   2. Effective June 16, 2008 neither PBSC nor marrow donors require an annual CBC.

C. Document each donor follow-up encounter by completing the Form 760, Post Donation – One Month, Six Months and Annual Donor Assessment at the specified time intervals.

D. Submit the form to the NMDP and maintain the original in the donor chart.

E. Coordinate study specific follow-up requirements (e.g. PBSC vs. Randomized Trial).

11.6. Encouraging Donor Participation in Follow-Up

A key step to ensuring successful donor participation is to emphasize the importance of the follow-up requirements in the information session with the donor. Listed below are tips for encouraging donor follow-up and the benefits of follow-up visits:

- Explain to the donor the importance of follow-up, which includes annual assessments.
  Note: If the donor was a PBSC vs. Marrow Randomized Trial participant, follow-up may also include a blood sample collection.
- Provide donor with a follow-up schedule at time of donation and, if possible, schedule follow-up appointments at this time.
- Remind donor of the next scheduled follow-up contact during current follow-up session.
- Use donor's preferred method of follow-up contact (e.g., phone, e-mail) and/or allow donor to contact the center.
- If blood draw is necessary (PBSC vs. Marrow Randomized Trial participant), call donor or send a reminder message prior to laboratory appointment.
- Thank the donor at each follow-up session and reiterate importance of collecting follow-up information.

Follow-Up Benefits:

- Donor safety
- Free blood "check-up" with CBC draw (if PVM donor)
- Reminder of their "gift of life" donation
- Benefit to future donors and recipients
- Advancing transplantation science and research

11.7. Donor Lost to Follow-Up

A donor may be declared lost to follow-up on a visit-by-visit basis or permanently if he or she refuses to participate in any future follow-up visits. A donor may only be declared lost to follow-up if the donor center has been unsuccessful in reaching the donor at the address and phone number on file, or the donor has requested not to be contacted.

All attempts and correspondence must be documented. Donors should be declared lost to follow-up only as a last resort. Depending upon the circumstances, complete and submit the appropriate form to the NMDP and maintain the original in the donor chart.

- Form 778, *Omitted Donor Follow-Up Visit* is completed when follow-up is omitted for that visit and is completed only on a visit-by-visit basis.
- Form 779, *Donor Follow-Up Withdrawal* is completed when the donor has requested not to be contacted and declines to participate in future follow-up. The donor center needs to have the request in writing from the donor or can document the verbal conversation with the donor in the donor's chart.

If no contact was attempted, a Protocol Deviation Form 3000 must be submitted for PBSC and PVM donors.

11.8. Donor Center Reimbursement

U.S. donor centers receive reimbursement for the coordination of the annual testing required during the post-donation follow-up process. Other follow-up reimbursement is part of the workup fee. See the *NMDP Fee-For-Service Policies and Reimbursement Procedures for specific information.* International donor centers receive reimbursement for services through separate mechanisms.

11.9. Post Donation and Post Transplant Confidentiality Guidelines

The need to maintain donor and recipient anonymity remains after stem cell collection and transplant. The objective is to ensure privacy for both the donor and recipient. For specific guidance on how to manage confidentiality during the search process, see the NMDP's *Donor and Patient Confidentiality Guidelines* on the NMDP Network Web site.

To protect donor anonymity after stem cell donation, the donor center must:

- Continue to screen all correspondence and/or gifts. Delete any reference that might allow the recipient or donor to identify the other individual

(location, names, identifying landmarks, etc.). Contact the SCU for additional assistance if necessary.

- Submit to the NMDP SCU all correspondence and/or gifts between an international donor and/or recipient. This communication must be screened by the NMDP Search and Transplant Services
- Inform the donor that NMDP policy does not permit the potential exchange of identifying donor information with the recipient until one-year post donation.
- Inform the donor that the regulations of some donor centers, transplant centers and cooperative registries may not ever allow donor and recipient pairs to meet or correspond directly, regardless of NMDP policy. See *NMDP International Centers Policies Regarding Post-Transplant Communication Between Donor and Recipient* for additional information.
- Obtain a signed consent from the donor if the donor would like to release personal information to the recipient. Explain the risks involved in such an action. Direct contact cannot occur unless signed consent form is obtained and on file for both the donor and recipient and at least one year has passed since the donation date.

11.10. Consent to Release Personal Information

It is an NMDP policy that donors and recipients cannot exchange information until one year post-donation. The donor center is responsible for notifying the transplant center of the donor's intent to release personal information by sending a copy of the document titled *Consent to Release a Donor's Personal Information*. Donor centers must follow the *Procedure to Obtain Consent to Release Donor Information*.

It is important to inform donors that some transplant centers do not permit direct contact with the recipient, and that there is no guarantee that the recipient will reciprocate. See the *NMDP International Centers Policies Regarding Post-Transplant Communication Between Donor and Recipient* for specific guidelines on communication with donors and recipients from international NMDP centers and cooperative registries.

The donor's decision to release personal information to the stem cell recipient is a personal one. A decision to release personal information must also be made by the recipient. While some donors will want to release information, others will make the decision to remain anonymous.

Personal information cannot be released until both the donor's and the patient's written consent is obtained and on file at both the donor center and the transplant center. The Transplant Amendment Act of 1990 defines penalties for anyone who

discloses the content of a donor record (for example, identity, address, HLA type or managing donor center) without prior written consent of the donor.

The Procedure to Obtain Consent to Release Donor Information, Consent to Release a Donor's Personal Information, and *NMDP International Centers Policies Regarding Post-Transplant Communication Between Donor and Recipient* are available on the Network Web site.

11.11. NMDP Donor Pins

Donors receive a special donor pin as a token of appreciation for their marrow or stem cell donation. The NMDP mails the pin and a personalized thank you letter to the donor center within one month of the stem cell collection. The donor center is responsible for forwarding both the pin and letter directly to the donor. Contact Donor Resources if the letter and pin are not received.

11.12. Donor Satisfaction Survey

A Donor Satisfaction survey is distributed to all donors who have completed the donation process, approximately one month post-donation. The purpose of the survey is to determine how satisfied donors are with their experience and to identify areas for improvement.

The survey focuses on the quality of the donor experience and donor retention. Key content areas to be evaluated are service access, service quality and the donor's experience with staff that provided service at the Donor Center, and Collection Center/Apheresis Center, as applicable.

The donor will remain anonymous unless they choose to contact the Donor Advocacy Program with additional information or questions. Survey results are tracked by both DC and CC/AC that provided service and the product type. Responses are compiled and aggregate results shared with the Network. Results for each center will be reported to that center, and specific issues will be shared with the involved center on a case by case basis.

11.13. Recipient Updates

NMDP Network transplant centers are expected to submit recipient update information to the SCU related to the recipient's status post-transplant. Donor centers should assess the donor's interest in receiving recipient updates. These updates are relayed to the donor center to allow the donor to be informed about the patient's progress. The donor center must provide accurate counsel to the donor about what to expect post-transplant. Although transplant centers are expected to submit updates in a timely manner, not all do. Some recipients may

decline to participate, but this will be conveyed on the form. Recipient updates are not available from a cooperative registry.

11.13.1. Recipient Updates (30 days, six months and one year)

Transplant centers are expected to submit recipient update information to the NMDP at 30 days, 6 months and one year post-transplant. Note that there is a two week grace period for the 30 day update, and a one month grace period for the six month and one year follow ups. The transplant center submits this information to the NMDP using the Forms 180/183/184 for the 30 day, six month and one year updates. The donor center receives this information via NMDP Web mail. Completed forms can also be accessed via FormsNet.

The recipient updates include the following information:

- The recipient's engraftment status (day 30 only)
- Current recipient status
- Additional optional comments

Donor centers will receive notification of completed Form 180/183/184. The information received should be shared with the donor if the donor desires to be informed of recipient updates.

11.13.2. Recipient Death Information

It is a requirement that transplant centers notify the CIBMTR if the recipient dies. When the transplant center provides this information to the CIBMTR, a notification of the recipient's death is sent to the donor center by NMDP Web mail. Due to privacy regulations, the exact date and/or cause of death cannot be shared.

When the SCU receives notification of the recipient's death, the search coordinator contacts the donor center via NMDP Webmail, fax or phone.

Donor centers are responsible for the following:

- Receive notification via NMDP Webmail.
- Review donor chart to see if the donor wants to receive recipient updates and when the last update occurred.
- Notify the donor by phone and/or letter.

【資料 9 】

NATIONAL MARROW DONOR PROGRAM®

Stem Cell Donor Follow-Up Evaluation

Registry Use Only

Sequence Number:

Date Received:

Donor NMDP ID: [ ][ ][ ][ ]-[ ][ ][ ][ ]-[ ]

Recipient NMDP ID: [ ][ ][ ]-[ ][ ][ ][ ]-[ ]

Most Recent Donation Date: [ ][ ] Month [ ][ ] Day 2 0 [ ][ ] Year ☐ n/a; filgrastim injection only
(For PBSC use Day 1 collection)

Most Recent Product Donated: ☐ Marrow ☐ PBSC

Donor Center Code: [ ][ ][ ][ ] Transplant Center Code: [ ][ ][ ][ ]

Apheresis / Collection Center Code: [ ][ ][ ][ ]

Follow-up visit for which this form is being completed:
☐ Day two (Form 777)
☐ One week (Form 780)
☐ Greater than one week (Form 781)

The donor should be contacted within 48 hours of the donation, at one week, and then weekly (or more often if necessary) until the donor reports full recovery.

1. Date of actual contact with the donor: [ ][ ] Month [ ][ ] Day 2 0 [ ][ ] Year

Conditions Present at Date of Contact

Using the following Modified Toxicity Criteria, review each body symptom with the donor. For each symptom associated with a system, select the statement that most closely reflects the donor's current condition.

In the Modified Toxicity Criteria below, the term "activities of daily living" (ADL) refers to tasks performed by individuals in a typical day that allow independent living. Basic activities of daily living include feeding, dressing, hygiene, and physical mobility.

Contact the NMDP Search Coordinating Unit to report any toxicities that are grade 3 or higher, and complete a Stem Cell Donor Adverse Event form.

Flu-Like Symptoms

2. Fever in absence of infections
   1 ☐ none (grade 0)
   2 ☐ 38.0 – 39.0° C / 100.0 – 102.2° F (grade 1)
   3 ☐ greater than 39.0 – 40.0° C / 102.2 – 104.0° F (grade 2)
   4 ☐ greater than 40.0° C / 104.0° F for **less** than 24 hours (grade 3)
   5 ☐ greater than 40.0° C / 104.0° F for **more** than 24 hours (grade 4)

Constitutional Symptoms

3. Fatigue (lethargy, malaise, asthenia)
   1 ☐ none (grade 0)
   2 ☐ mild fatigue over baseline (grade 1)
   3 ☐ moderate or causing difficulty performing some ADL (grade 2)
   4 ☐ severe fatigue interfering with ADL (grade 3)
   5 ☐ disabling (grade 4)

If not using the NMDP FormsNet™ application, a copy of this completed form may be mailed to:
National Marrow Donor Program
Suite 100
3001 Broadway St. N.E.
Minneapolis, MN 55413
Retain original at the Donor Center.

Internal use: Document number F00171 revision 3 Replaces: F00171 version 2.0

Dermatologic

4. Rashes on skin
   1 ☐ none (grade 0)
   2 ☐ macular or papular eruption or erythema that is asymptomatic (discrete areas of raised or flat, discolored and/or reddened skin patches, with no other symptoms) (grade 1)
   3 ☐ macular or papular eruption or erythema with pruritus or other associated symptoms (same as above in conjunction with symptoms such as itching and pain) (grade 2)
   4 ☐ severe, generalized erythroderma or macular, papular, or vesicular eruption (same as above with the possible addition of fluid-filled blisters; also, the condition is not widely spaced, but instead covers the majority of the body) (grade 3)
   5 ☐ generalized exfoliative dermatitis or ulcerating dermatitis (skin inflammation leading to peeling and/or ulceration) (grade 4)
5. Injection site reaction (filgrastim, IV, or marrow collection)
   1 ☐ none (grade 0)
   2 ☐ pain; itching; erythema (grade 1)
   3 ☐ pain and swelling with inflammation or phlebitis (grade 2)
   4 ☐ ulceration or necrosis that is severe; operative intervention indicated (grade 3)

Gastrointestinal

6. Nausea
   1 ☐ none (grade 0)
   2 ☐ loss of appetite without alteration in eating habits (grade 1)
   3 ☐ oral intake decreased without significant weight loss, dehydration or malnutrition (grade 2)
   4 ☐ inadequate oral caloric or fluid intake (grade 3)
   5 ☐ life-threatening consequences (grade 4)
7. Vomiting
   1 ☐ none (grade 0)
   2 ☐ 1 episode in 24 hours (grade 1)
   3 ☐ 2–5 episodes in 24 hours (grade 2)
   4 ☐ 6 or more episodes in 24 hours (grade 3)
   5 ☐ life-threatening consequences (grade 4)
8. Loss of appetite (anorexia)
   1 ☐ none (grade 0)
   2 ☐ loss of appetite without alteration in eating habits (grade 1)
   3 ☐ altered intake without significant weight loss or malnutrition (grade 2)
   4 ☐ significant weight loss or malnutrition (grade 3)
   5 ☐ life-threatening (grade 4)

Neurological

9. Inability to sleep (insomnia)
   1 ☐ normal (grade 0)
   2 ☐ occasional difficulty sleeping, not interfering with function (grade 1)
   3 ☐ difficulty sleeping, interfering with function but not interfering with ADL (grade 2)
   4 ☐ frequent difficulty sleeping, interfering with ADL (grade 3)
   5 ☐ disabling (grade 4)
10. Dizziness, vertigo, or lightheadedness
    1 ☐ none (grade 0)
    2 ☐ with head movements only; not interfering with function (grade 1)
    3 ☐ interfering with function, but not interfering with ADL (grade 2)
    4 ☐ interfering with ADL (grade 3)
    5 ☐ disabling (grade 4)
11. Fainting (syncope)
    1 ☐ none (grade 0)
    2 ☐ present (grade 3)
    3 ☐ life-threatening consequences (grade 4)

Internal use: Document number F00171 revision 3 Replaces: F00171 version 2.0

Follow-up Visit: ☐ Day two ☐ One week ☐ Greater than one week

Donor NMDP ID: [ ][ ][ ][ ]-[ ][ ][ ][ ]-[ ]

Sites of Pain

For each of the sites listed below, indicate the severity of pain present using the following scale:
0 = none (grade 0)
1 = mild pain not interfering with function (grade 1)
2 = moderate pain interfering with function but not ADL (grade 2)
3 = severe pain severely interfering with ADL (grade 3)
4 = disabling (grade 4)

12. Back	0 ☐ none (grade 0)	1 ☐ mild (grade 1)	2 ☐ moderate (grade 2)	3 ☐ severe (grade 3)	4 ☐ disabling (grade 4)
13. Bones (including sternum and ribs)	0 ☐ none (grade 0)	1 ☐ mild (grade 1)	2 ☐ moderate (grade 2)	3 ☐ severe (grade 3)	4 ☐ disabling (grade 4)
14. Headache	0 ☐ none (grade 0)	1 ☐ mild (grade 1)	2 ☐ moderate (grade 2)	3 ☐ severe (grade 3)	4 ☐ disabling (grade 4)
15. Hip	0 ☐ none (grade 0)	1 ☐ mild (grade 1)	2 ☐ moderate (grade 2)	3 ☐ severe (grade 3)	4 ☐ disabling (grade 4)
16. IV site	0 ☐ none (grade 0)	1 ☐ mild (grade 1)	2 ☐ moderate (grade 2)	3 ☐ severe (grade 3)	4 ☐ disabling (grade 4)
17. Joints (excluding hip)	0 ☐ none (grade 0)	1 ☐ mild (grade 1)	2 ☐ moderate (grade 2)	3 ☐ severe (grade 3)	4 ☐ disabling (grade 4)
18. Limbs (arms, legs, hands, feet)	0 ☐ none (grade 0)	1 ☐ mild (grade 1)	2 ☐ moderate (grade 2)	3 ☐ severe (grade 3)	4 ☐ disabling (grade 4)
19. Muscles	0 ☐ none (grade 0)	1 ☐ mild (grade 1)	2 ☐ moderate (grade 2)	3 ☐ severe (grade 3)	4 ☐ disabling (grade 4)
20. Neck	0 ☐ none (grade 0)	1 ☐ mild (grade 1)	2 ☐ moderate (grade 2)	3 ☐ severe (grade 3)	4 ☐ disabling (grade 4)
21. Throat	0 ☐ none (grade 0)	1 ☐ mild (grade 1)	2 ☐ moderate (grade 2)	3 ☐ severe (grade 3)	4 ☐ disabling (grade 4)
22. Other pain site:	0 ☐ none (grade 0)	1 ☐ mild (grade 1)	2 ☐ moderate (grade 2)	3 ☐ severe (grade 3)	4 ☐ disabling (grade 4)

23. Specify pain site: _____

24. Has the donor recovered from donation and returned to his or her baseline condition?
1 ☐ yes
2 ☐ no →

25. Are the donor's symptoms related to the stem cell collection?
1 ☐ definitely related
2 ☐ probably related
3 ☐ possibly related
4 ☐ unlikely related

26. Is there a scheduled follow-up date?
1 ☐ yes →
2 ☐ no

27. Next follow-up date: [ ][ ] [ ][ ] [2][0][ ][ ]
Month Day Year

28. Notes on Follow-Up *(optional)*: _____

29. Signed: _____
Person completing form

Please print first and last name: _____

Date: _____

Preferred method of contact: _____
Phone number or e-mail address

【資料 10 】

NATIONAL MARROW DONOR PROGRAM®

Post-Donation – One Month, Six Months, and One Year Donor Assessment

Registry Use Only

Sequence Number:

Date Received:

Donor NMDP ID: ☐☐☐☐-☐☐☐☐-☐

Recipient NMDP ID: ☐☐☐-☐☐☐-☐

DC Code: ☐☐☐ TC Code: ☐☐☐☐

Date of Collection: ☐☐ (Month) ☐☐ (Day) 20☐☐ (Year) ☐ n/a; filgrastim injection only

Product type: ☐ Marrow ☐ PBSC

Date of Medical Evaluation from Form 700: ☐☐ (Month) ☐☐ (Day) 20☐☐ (Year)

Follow-up visit for which this form is being completed:
☐ One month (Form 760)
☐ Six months (Form 761)
☐ One year (Form 762)

1. Date of actual contact with the donor: ☐☐ (Month) ☐☐ (Day) 20☐☐ (Year)

Conditions Present on Day of Contact

Using the following Modified Toxicity Criteria, review each body symptom with the donor. For each symptom associated with a system, select the statement that most closely reflects the donor's current condition.

In the Modified Toxicity Criteria below, the term "activities of daily living" (ADL) refers to tasks performed by individuals in a typical day that allow independent living. Basic activities of daily living include feeding, dressing, hygiene, and physical mobility.

Contact the NMDP Search Coordinating Unit to report any toxicities that are grade 3 or higher, and complete a Stem Cell Donor Adverse Event Form.

Flu-Like Symptoms

2. Fever in absence of infections
   1 ☐ none (grade 0)
   2 ☐ 38.0 – 39.0° C / 100.0 – 102.2° F (grade 1)
   3 ☐ greater than 39.0 – 40.0° C / 102.2 – 104.0° F (grade 2)
   4 ☐ greater than 40.0° C / 104.0° F for less than 24 hours (grade 3)
   5 ☐ greater than 40.0° C / 104.0° F for more than 24 hours (grade 4)

Constitutional Symptoms

3. Fatigue (lethargy, malaise, asthenia)
   1 ☐ none (grade 0)
   2 ☐ mild fatigue over baseline (grade 1)
   3 ☐ moderate or causing difficulty performing some ADL (grade 2)
   4 ☐ severe fatigue interfering with ADL (grade 3)
   5 ☐ disabling (grade 4)

Dermatologic

4. Rashes on skin
   1 ☐ none (grade 0)
   2 ☐ macular or papular eruption or erythema that is asymptomatic (discrete areas of raised or flat, discolored and/or reddened skin patches, with no other symptoms) (grade 1)
   3 ☐ macular or papular eruption or erythema with pruritus or other associated symptoms (same as above in conjunction with symptoms such as itching and pain) (grade 2)
   4 ☐ severe, generalized erythroderma or macular, papular, or vesicular eruption (same as above with the possible addition of fluid-filled blisters; also, the condition is not widely spaced, but instead covers the majority of the body) (grade 3)
   5 ☐ generalized exfoliative dermatitis or ulcerating dermatitis (skin inflammation leading to peeling and/or ulceration) (grade 4)

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5. Injection site reaction (filgrastim, IV, or marrow collection)
   1 ☐ none (grade 0)
   2 ☐ pain; itching; erythema (grade 1)
   3 ☐ pain and swelling with inflammation or phlebitis (grade 2)
   4 ☐ ulceration or necrosis that is severe; operative intervention indicated (grade 3)

Gastrointestinal

6. Nausea
   1 ☐ none (grade 0)
   2 ☐ loss of appetite without alteration in eating habits (grade 1)
   3 ☐ oral intake decreased without significant weight loss, dehydration or malnutrition (grade 2)
   4 ☐ inadequate oral caloric or fluid intake (grade 3)
   5 ☐ life-threatening consequences (grade 4)

7. Vomiting
   1 ☐ none (grade 0)
   2 ☐ 1 episode in 24 hours (grade 1)
   3 ☐ 2–5 episodes in 24 hours (grade 2)
   4 ☐ 6 or more episodes in 24 hours (grade 3)
   5 ☐ life-threatening consequences (grade 4)

8. Loss of appetite (anorexia)
   1 ☐ none (grade 0)
   2 ☐ loss of appetite without alteration in eating habits (grade 1)
   3 ☐ altered intake without significant weight loss or malnutrition (grade 2)
   4 ☐ significant weight loss or malnutrition (grade 3)
   5 ☐ life-threatening (grade 4)

Neurological

9. Inability to sleep (insomnia)
   1 ☐ normal (grade 0)
   2 ☐ occasional difficulty sleeping, not interfering with function (grade 1)
   3 ☐ difficulty sleeping, interfering with function but not interfering with ADL (grade 2)
   4 ☐ frequent difficulty sleeping, interfering with ADL (grade 3)
   5 ☐ disabling (grade 4)

10. Dizziness, vertigo, or lightheadedness
    1 ☐ none (grade 0)
    2 ☐ with head movements only; not interfering with function (grade 1)
    3 ☐ interfering with function, but not interfering with ADL (grade 2)
    4 ☐ interfering with ADL (grade 3)
    5 ☐ disabling (grade 4)

11. Fainting (syncope)
    1 ☐ none (grade 0)
    2 ☐ present (grade 3)
    3 ☐ life-threatening consequences (grade 4)

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13 ☐ colorectal cancer
14 ☐ kidney (renal cell) cancer
15 ☐ lung cancer
16 ☐ melanoma in situ
17 ☐ melanoma, invasive
18 ☐ non-melanoma skin cancer (e.g., basal cell, squamous)
19 ☐ oral cavity / pharynx
20 ☐ ovarian cancer
21 ☐ pancreatic cancer
22 ☐ prostate cancer
23 ☐ testicular cancer
24 ☐ thyroid cancer
25 ☐ uterine cancer
26 ☐ other cancer → 30. Specify other cancer: _____

Specify if the donor developed any of the following diseases since the date of the last report:

31. Systemic lupus erythematosus (SLE, lupus)
1 ☐ yes → 32. Specify date of diagnosis: ☐☐ (Month) 20☐☐ (Year)
2 ☐ no

33. Rheumatoid arthritis (RA)
1 ☐ yes → 34. Specify date of diagnosis: ☐☐ (Month) 20☐☐ (Year)
2 ☐ no

35. Vasculitis, inflammation or autoimmune disease of blood vessels
1 ☐ yes → 36. Specify date of diagnosis: ☐☐ (Month) 20☐☐ (Year)
2 ☐ no

37. Thrombosis (including DVT and thrombophlebitis)
1 ☐ yes → 38. Specify date of diagnosis: ☐☐ (Month) 20☐☐ (Year)
2 ☐ no

39. Multiple sclerosis (MS)
1 ☐ yes → 40. Specify date of diagnosis: ☐☐ (Month) 20☐☐ (Year)
2 ☐ no

41. Idiopathic thrombocytopenic purpura (ITP), autoimmune disease of platelets
1 ☐ yes → 42. Specify date of diagnosis: ☐☐ (Month) 20☐☐ (Year)
2 ☐ no

43. Other autoimmune disorder
1 ☐ yes → 44. Specify other autoimmune disorder: _____
45. Specify date of diagnosis: ☐☐ (Month) 20☐☐ (Year)
2 ☐ no

Follow-up Visit: ☐ One month ☐ Six months ☐ One year Donor NMDP ID: ☐☐☐☐–☐☐☐☐–☐

46. Contact information of physician providing treatment for any conditions listed in questions 26–45: ☐ not applicable

Physician's first and last name: _____
Medical facility: _____
Address: _____
City, State, Zip code: _____
Phone: (_____) _____ Fax: (_____) _____
E-mail address: _____

47. Additional notes on donor assessment: *(optional)* _____

48. Signed: _____
Person completing form
Please print first and last name: _____
Date: _____
Preferred method of contact: _____
Phone number or e-mail address

研究項目： 非血縁者間末梢血幹細胞移植法の臨床試験体制確立に関する研究
分担研究員： 神田　善伸先生

厚生労働科学研究費補助金（免疫アレルギー疾患等予防・治療研究事業）
研究分担者報告書

「非血縁者間末梢血幹細胞移植の臨床試験体制確立」に関する研究

研究分担者　神田　善伸
自治医科大学附属さいたま医療センター血液科

研究要旨
同種末梢血幹細胞移植を非血縁者間で行うにあたり、同種骨髄移植と比較した優劣を明らかにするための臨床研究が必要になる。しかし、同種末梢血幹細胞移植に関しては、国内での経験が皆無に等しい状況であり、当面は経験を蓄積し、非血縁者間末梢血幹細胞移植手法の至適化を急ぐべきであろう。本分担研究では、生着までの期間が短い非血縁者間末梢血幹細胞移植を選択すべき理由の一つとして、移植後早期感染症の高リスク群を同定する試みを行った。残念ながら高感度CRPによる感染症高リスク群の同定は困難であることがわかり、今後は他の因子を用いたリスク分類を試みる。

A．研究目的

同種末梢血幹細胞移植を非血縁者間で行うにあたり、同種骨髄移植と比較した優劣を明らかにするための臨床研究が必要になる。しかし、同種末梢血幹細胞移植に関しては、国内での経験が皆無に等しい状況であり、臨床試験を計画するための基礎的データすら存在しない。そこで、当面は経験を蓄積し、そのデータに基づいて非血縁者間末梢血幹細胞移植単群での臨床試験を行い、手法の至適化を急ぐべきであろう。その結果に応じて非血縁者間骨髄移植との無作為割付比較試験の実施や、医療費、QOL も評価に含めた臨床決断分析などの実施を検討する。

将来的に患者側で骨髄移植と末梢血幹細胞移植のいずれかを選択できるようになるとすると、末梢血幹細胞移植を選択する理由の一つとして、生着までの期間が短縮され、移植後早期の感染症が減少するということが考えられる。研究分担者らは以前に急性骨髄性白血病の対する地固め療法前の高感度CRP値によって、好中球減少期間に生じるfebrile neutropenia（FN）やdocumented infection（DI）などの感染症イベントの発生率を予測できることを示した。そこで、本分担研究では、生着までの期間が短い非血縁者間末梢血幹細胞移植を選択すべき理由の一つとして、造血幹細胞移植前の高感度CRP値によって移植後早期感染症の高リスク群を同定する試みを行った。

B．研究方法

2006年4月から2009年3月までに当院で同種あるいは自家造血幹細胞移植を行った患者 70 例［同種移植46例（血縁28例、非血縁18例）、自家移植 24 例］を対象とした。前処置施行前に発熱や感染症の合併、あるいは静注抗菌薬が投与されていた症例、生着不全を生じた症例は除外した。前処置施行直前の高感度CRP値（ラテックス免疫比濁法）を測定し、生着後1週間までの期間のFNやDIの有無を評価し、ROC曲線を用いてCRP値の

適切な閾値と感度、特異度、陽性適中率（PPV)、陰性適中率（NPV）を検討した。

C．研究結果

FNはほとんどの患者に認められたため、高感度CRPによる予測は不可能であった。DIについても、ROC曲線AUCは自家移植で0.59、同種移植でAUC 0.57で、予測能力は地固め療法時(AUC 0.67)よりも低下していた。自家移植では閾値 0.22 mg/dLにおいて感度0.60、特異度0.59、PPV 0.30、NPV 0.83、同種移植では閾値 0.23 mg/dL において感度0.58、特異度0.69、PPV 0.69、NPV 0.58であった。

D.考察

造血幹細胞移植前の高感度CRP値測定のFN、DI発症予測能は地固め療法時よりも劣る傾向がみられた。造血幹細胞移植の前処置は地固め療法より強力で長期間の好中球減少や粘膜障害を伴うため、前処置後の様々な因子の影響が感染症と関連するために前処置前のCRP値による感染症イベント発症予測の妨げになっている可能性が考えられた。

F．研究発表

本研究の結果から、造血幹細胞移植前の高感度CRP値によって移植後早期の感染症イベントの発生率を予測することは困難であることが示された。非血縁者間骨髄移植において末梢血幹細胞移植を選択すべき患者の同定には他の因子を用いた感染症リスクの評価が必要である。

論文発表

1. Sato M, Kako S, Oshima K, Sato K, Terasako K, Kimura SI, Nakasone H, Okuda S, Yamazaki R, Higuchi T, Nishida J, Kanda Y. Prediction of infectious events by high-sensitivity C-reactive protein (CRP) level before undergoing chemotherapy for acute myeloid leukemia. Scandinavian Journal of Infectious Diseases (in press)

2. Kimura SI, Oshima K, Okuda S, Sato K, Sato M, Terasako K, Nakasone H, Kako S, Yamazaki R, Tanaka Y, Tanihara A, Higuchi T, Nishida J, Kanda Y. Pharmacokinetics of cyclosporine during the switch from continuous intravenous infusion to oral administration after allogeneic hematopoietic stem cell transplantation. Bone Marrow Transplantation (in press)

3. Kanda Y, Yamashita T, Mori T, Ito T, Tajika K, Mori S, Sakura T, Hara M, Mitani K, Kurokawa M, Akashi K, Harada M. A randomized controlled trial of plasma real-time PCR and antigenemia assay for monitoring cytomegalovirus infection after unrelated bone marrow transplantation. Bone Marrow Transplantation (in press)

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1. 佐藤美樹、金子久美、賀古真一、佐藤謙、寺迫桐子、木村俊一、仲宗根秀樹、奥田慎也、山崎理絵、樋口敬和、西田淳二、神田善伸　造血幹細胞移植前処置直前の高感度CRP値による好中球減少時の感染症イベント予測 第71回日本血液学会総会　2009年10月

G．知的財産権の出願・登録状況

該当事項なし