



CIBMTR[®]

CENTER FOR INTERNATIONAL BLOOD
& MARROW TRANSPLANT RESEARCH

Supplemental Form 2509 Intravenous Busulfan Study

General Instructions for Form 2509

Study SC09-01 is a prospective, observational cohort study using data reported to CIBMTR. It compares outcomes for patients receiving a first allogeneic transplant with myeloablative conditioning using intravenous busulfan in combination with other agents, versus patients receiving a first allogeneic transplant with myeloablative conditioning with total body irradiation (TBI) in combination with other agents.

This Form 2509 is a supplement to the CIBMTR comprehensive Report Form (cRF). It should be completed for hematopoietic stem cell transplant (HSCT) recipients who were treated with intravenous busulfan plus cyclophosphamide or fludarabine in the pre-HSCT preparative regimen, who were selected for this study. It asks a few follow-up study and confirmatory questions related to the patient's preparative regimen and pharmacokinetic testing. This supplemental form is due at the same time as Form 2000, Recipient Baseline Data. Patients enrolled in the TBI cohort do not require this supplemental form.

If a recipient is being transplanted for AML or CML and has active CNS leukemia at the time of the transplant (as reported on the pre-HSCT disease-specific form), they will be removed from the study.

ERROR CORRECTION

Any changes or corrections that must be made to forms that were previously submitted should be sent to CIBMTR via FormsNet™2, or by sending a paper Error Correction form to your center's assigned campus (Milwaukee or Minneapolis). Paper forms can be downloaded from:

http://www.cibmtr.org/DATA/Data_Mgmt_Forms/index.html

Questions about this form should be directed to the Study Coordinator, Jeanne Dobratz, at jdobratz@mcw.edu

CIBMTR Center Number:

DIRECTIVE: This new 5-digit number *replaces* the former 3-digit CIBMTR *Team number* and NMDP *TC code*.

CIBMTR Recipient ID (CRID):

DIRECTIVE: The CRID is meant to be a lifelong ID number for the recipient. It is assigned on completion of the Unique ID Assignment/CRID Form (2804). Do NOT report the recipient's IUBMID or NMDP RID numbers.

Today's Date:
 Month Day Year

DIRECTIVE: Use date this document was completed and checked for accuracy by the center.

Date of HSCT for which this form is being completed:
 Month Day Year

DIRECTIVES: Date of HSCT should reflect the date of the patient's *first* allogeneic HSCT. Patients who have had a previous allogeneic HSCT **are not** eligible for this study. Patients who have had a previous **autologous** transplant **are** eligible. If this is not the first allogeneic transplant for the patient, please review what was reported on CIBMTR Form 2400, Pre-Transplant Essential Data (Pre-TED). If the chronological number for this HSCT and the previous HSCT were not conveyed accurately, please submit an Error Correction as described above.

If the patient is on the cRF track, had a previous autologous HSCT reported to CIBMTR and this form is being completed for a subsequent allogeneic HSCT, please review the Subsequent HSCT section of the most recent CIBMTR Follow-up Report Form (2100, 2200, or 2300) that was submitted for the previous HSCT. If dates are inaccurate, please submit an Error Correction.

DEFINITION(S):

Autologous: The recipient is his or her own donor.

Allogeneic, unrelated: The donor is a different person from the recipient, is not related by birth to the recipient. Usually found through an unrelated donor registry.

Allogeneic, related: The donor is a different person from the recipient and is a relative (sibling, child, parent, etc.) of the recipient.

Syngeneic: monozygotic twin (one zygote or egg, paternal twin), identical twin. (Do not confuse with the term HLA-identical sibling.)

HSCT type: autologous allogeneic, unrelated allogeneic, related syngeneic (identical twin)

DIRECTIVES: HSCT type should reflect an allogeneic (related or unrelated) transplant. If not, please review what was reported on the Form 2400, the Pre-TED form. If the HSCT type was not conveyed accurately, please submit an Error Correction.

If the patient is on the cRF track, had a previous autologous HSCT reported to CIBMTR, and this form is being completed for a subsequent allogeneic HSCT, please review what was reported on Form 2000, Recipient Baseline Data.

Also, verify that the correct HSCT type was reported in the Subsequent HSCT section for the most recent Follow-up Report Form (2100, 2200, or 2300), which was submitted for the previous HSCT. If the HSCT type was not conveyed accurately, please submit an Error Correction.

Product type: Marrow PBSC Cord blood
 Multiple cord blood units infused Other product (Specify): _____

DIRECTIVES: Product type should reflect marrow and/or peripheral blood stem cells (PBSC). If not, please review what was reported on Form 2400, Pre-TED. If the Product type was not conveyed accurately on the Pre-TED form, please submit an Error Correction.

If the patient is on the cRF track, had a previous autologous HSCT reported to CIBMTR, and this form is being completed for a subsequent allogeneic HSCT, please review what was reported on the Form 2000, Recipient Baseline Data. If the Product type was not conveyed accurately on that form, please submit an Error Correction.

Also, please verify that the correct product type was reported in the Subsequent HSCT section of the most recent Follow-up Report Form (2100, 2200, or 2300) that was submitted for the previous HSCT.

STUDY QUESTIONS

QUESTION 1: Busulfan was indicated on the pre-Ted as being part of the planned preparative regimen, per protocol. Was IV busulfan actually given?

Yes No

DIRECTIVES: Accurate information about drugs used and dosage is crucial to evaluating transplant regimens. These are central questions to this study. If the patient did not receive IV busulfan, please correct Form 2400, the Pre-TED form.

If the patient did not receive IV busulfan, please jump to the signature lines at question 14.

If the patient is on the cRF track, had a previous autologous HSCT reported to CIBMTR, and this form is being completed for a subsequent allogeneic HSCT, please review what was reported on the Form 2000, Recipient Baseline Data. If IV busulfan use was not conveyed accurately on that form, please submit an Error Correction.

EXAMPLES for Questions 2-5.

1. Patient's transplant protocol reads: IV busulfan at 0.8 mg/kg every 6 hours for 16 doses.

The **total prescribed cumulative dose** would be "12.8 mg/kg."

The **dosing schedule** would be "every 6 hours."

The **total duration of administration** would be "16 doses."

2. Patient's transplant protocol reads: IV busulfan at 3.2 mg/kg daily for 3 days.

The **total prescribed cumulative dose** would be "9.6 mg/kg."

The **dosing schedule** would be "daily."

The **total duration of administration** would be "3 days."

QUESTION 2: Specify the **total prescribed cumulative dose** for the preparative regimen (per the protocol):

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Specify units 1 mg/m²
2 mg/kg

DIRECTIVES: The intent of the preparative regimen section on Form 2400, Pre-TED, is to capture accurate information regarding drugs used and dosage, which are crucial to the evaluation of transplant regimens. Report the **total prescribed cumulative dose** to be given as prescribed in the transplant protocol or standard of care (not the administration frequency dose). The form is designed to capture the **protocol regimen only**. Indicate which **units** are appropriate for the dose. If available records do not list the units, please consult with the transplant pharmacist.

If the intended dose was not the actual dose, **DO NOT** send corrected information. The actual total dose received is reported in Form 2000, Recipient Baseline Data. If the total dose is adjusted for any reason, such as a result of test dosing or dose modifications, that information will be captured on the Baseline Form.

Compare what was reported on the 2400, Pre-TED form to the medical record: was the planned dose conveyed accurately on the Pre-TED? If not, please submit an Error Correction.

The busulfan preparative regimen data reported on the Pre-TED form and in question 2 of this form should match. **NOTE:** The Pre-TED dose should be rounded up or down to exclude the decimal value.

If the patient is on the cRF track, had a previous autologous HSCT reported to CIBMTR, and this form is being completed for a subsequent allogeneic HSCT, a Pre-TED form (2400) was not required. Please answer question 2 and report the actual total dose received on Form 2000, Recipient Baseline Data.

QUESTION 3: How was the busulfan administration scheduled for the regimen?

- Every six hours**
- Daily**
- Twice Daily**
- Other schedule**

QUESTION 4: Specify **other** frequency of busulfan administration:

DIRECTIVES: Report the planned dosing schedule for IV busulfan as part of the preparative regimen of question 2. If the dosing schedule used for the patient is not listed here, please supply that information in question 4.

QUESTION 5: Specify **planned total** administration duration:

		Total		Doses
				Days

DIRECTIVES: Report the numerical value for the total duration of administration of IV busulfan as part of the preparative regimen in question 2. Check the appropriate box for that duration. *Using the first example above, "16" would be the numerical value and the "doses" box would be checked.*

DEFINITION:
Pharmacokinetics (PK): Testing that involves serial acquisition of blood samples following administration of a dose of a drug, where each sample is tested for drug concentration to determine an individual's ability to metabolize or eliminate the drug.

QUESTION 6: Were pharmacokinetics performed to determine preparative regimen drug dosing?

Yes **No**

DIRECTIVES: Information regarding the use of pharmacokinetic testing to determine the preparative regimen busulfan dosing is essential to the study. Compare what was reported on Form 2000, Recipient Baseline Data, question 367, to the medical record: was pharmacokinetic testing accurately conveyed on the form? If not, please correct the Baseline Form via an Error Correction. If pharmacokinetics were not performed, please jump to the signature lines at question 14.

QUESTION 7: Were pharmacokinetics performed prior to administration of the preparative regimen with a test dose?

Yes **No**

QUESTION 8: Were pharmacokinetics performed during administration of the preparative regimen?

Yes **No**

DIRECTIVES: Check all applicable boxes for when pharmacokinetics were performed.

QUESTION 9: Specify the pharmacokinetic target level of busulfan.

Concentration steady-state plasma level (C_{ss})

10. Specify the busulfan C _{ss} target level: <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> ng/mL
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Area under the plasma concentration time curve (AUC)

11. Specify the busulfan AUC target level: <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> µM X min

DIRECTIVES: Check the box for the target level of busulfan. This information can typically be found within the recipient’s treatment planner, face sheet, medical record or PK requisition form. Then, report the actual busulfan target level. If the target level is a range, then report the minimum of that range.

QUESTION 12: Was a plan in place to adjust the dose of IV busulfan based on the results of the pharmacokinetics?

Yes **No**

DIRECTIVES: If yes, continue to question 13. If no, jump to the signature lines at question 14.

QUESTION 13: Was the busulfan dose adjusted based on the pharmacokinetics?

Yes **No**

DIRECTIVES: Report whether the busulfan dose was adjusted based on the pharmacokinetic testing. A review of the physician orders or pharmacy records for the patient may be needed to determine whether the dose was changed. Most frequently, dose changes occur on the second day of drug administration.

QUESTION 14: CONTACT INFORMATION for person filling out this form (or person who can answer queries about the information).

Name	E-mail	Phone #	Fax #	Signature
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