Pediatric Heart Network: Trial of BB vs. ARB in Marfan Syndrome

PHN-06   251

Form A300: Clinical Assessment at Time of Echocardiography

INSTRUCTIONS: If this form is being completed for a baseline echocardiogram, the form must be completed and entered into ADEPT prior to randomization.

Section A: KEY IDENTIFYING INFORMATION

A1.   Study Identification Number   ___ ___ - ___ ___ ___ ___ ___ ___ - ___

A2.   Study Visit   BASELINE 0

                                                        STUDY VISIT 1 (Month 6) .... 1 **(A3)**

                                                        STUDY VISIT 2 (Month 12) .... 2 **(A3)**

                                                        STUDY VISIT 3 (Month 24) .... 3 **(A3)**

                                                        STUDY VISIT 4 (Month 36) .... 4 **(A3)**

                                                        WITHDRAWAL FROM TRIAL..................... 9 **(A3)**

     a.   What number screening is this?   ___

A3.   Date of form completion   ___ ___ / ___ ___ / ___ ___ ___ ___
                                                        M   M   D   D   Y   Y   Y   Y

A4.   Name of person completing form   _____ ___ ___ ___
                                                                  PRINT FULL NAME   INITIALS

A5.   Was an echocardiogram obtained?   YES .... 1 (**A6**)   NO 2

    a.   Reason not obtained   _____

	SKIP TO Z1

A6.   Date of echocardiogram   ___ ___ / ___ ___ / ___ ___ ___ ___
                                                        M   M   D   D   Y   Y   Y   Y

A7.   (Blinded) Echo ID   ___ ___ - ___ ___ ___ ___ ___ ___ - ___
                                              Enter Echo ID used to make anonymous the image files to be sent
                                              via FTP

Section B: CLINICAL ASSESSMENT AT ECHOCARDIOGRAM

1. **Record the following information collected on the <u>same day</u> as the study echocardiogram.**
2. **Record weight and length or height measurements obtained by the <u>Marfan Trial Study Coordinator</u>. If Measures 1 and 2 for questions B1 and B2 differ by more than the stated amount in the "Difference" column, a third measurement must be taken.**
3. **Record blood pressure and heart rate values at or near the time of <u>recording of the aortic dimension data with the subject in the supine position.</u>**

	a. **Measure 1**	**b.** **Measure 2**	**Difference**	**c.** **Measure 3**
B1. Weight (kg)	__ __ __ . __	__ __ __ . __	**> 0.1 kg ➜**	__ __ __ . __
B2. Length (cm)	__ __ __ . __	__ __ __ . __	**> 1.0 cm ➜**	__ __ __ . __

     d.   How measured?   STANDING 1

                                              RECUMBENT 2

B3. Systolic BP   __ __ __ mm Hg

B4. Diastolic BP   __ __ __ mm Hg

B5. Mean BP   __ __ __ mm Hg

B6. Heart rate   __ __ __ beats/minute

Answer question B7 for the <u>baseline study</u> echocardiogram only. The value reported for B7 will be used to calculate the subject's aortic root Z-score for eligibility purposes.

B7. Subject's maximum **systolic** aortic root dimension at the sinuses of Valsalva from the <u>baseline study</u> echocardiogram   __ . __ __ cm

B8. Sedation   NO SEDATION 1

                                         CONSCIOUS SEDATION 2

                                         GENERAL ANESTHESIA 3

B9. Sinus or ectopic atrial rhythm   YES 1   NO 2   INDETERMINATE .... -8

                             IF YES, GO TO B10   ⬇   **IF INDETERMINATE, GO TO B10**

    a.   Complete heart block   YES 1   NO 2   INDETERMINATE .... -8

    b.   Paced rhythm   YES 1   NO 2   INDETERMINATE .... -8

    c.   Atrial flutter/fibrillation   YES 1   NO 2   INDETERMINATE .... -8

B10. Name of ultrasonographer [Physician or technician] who acquired the images
(**See Sonographer Table**)

___ ___ ___   _____   _____

a. INITIALS   b. FIRST NAME   c. LAST NAME

B11. Site code for echo lab location   ___ ___ ___
(**See Code List Q: Marfan Syndrome Trial Sites)**

Section Z: TIME TO COMPLETE FORM

Z1.   How long did it take to complete this form?   ___ ___ ___ minutes

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END OF FORM

If this form was completed for the <u>baseline</u> echocardiogram, run the "A300" Report in ADEPT to see the calculated baseline aortic root Z-score.

SEE MANUAL OF OPERATIONS FOR INSTRUCTIONS REGARDING LABELING OF ECHO STUDIES AND TRANSFER OF IMAGE FILES TO THE CORE LAB.