DAC Study Form 304 - Fistula Patency

This form is completed, along with the "visit" form (333) and the QOL form 341, six weeks after the surgery. If the study drug was discontinued because of fistula thrombosis prior to six weeks, this form and the "visit" form 333 are completed 30 days after study drug is discontinued or at six weeks, whichever comes first. (Patency assessment only counts if it is done 40 to 50 days after surgery)

1. Patient Identification Number.....__ __ __ __ __ __

   a. Patient Name Code .....__ __ __ __

   b. Date of this six week visit..... __ __ /__ __/__ __ __ __

   c. Was there a one day call to check on compliance?.....__

      (0=no, 1=yes, 9=unknown)

   d. Date of the one day call ..... __ __ / __ __ / __ __ __ __

   e. Was there a two week call to check on compliance and adverse events? .....__

      (0=no, 1=yes, 9=unknown)

   f. Date of the two week call ..... __ __ / __ __ / __ __ __ __

   Note: If there is an adverse event reported, make sure to file Form 333 and any other forms referred by it.

   g. Was there a four week call to check on compliance and adverse events? .....__

      (0=no, 1=yes 9=unknown)

   h. Date of the four week call..... __ __ / __ __ / __ __ __ __

   Note: If there is an adverse event reported, make sure to file Form 333 and any other forms referred by it.

2. a. Date the fistula placed..... __ __ /__ __/__ __ __ __

   b. Where was it placed (location of the surgical center)?.....__ __ __ __
      (See the codes for the hospitals from Form 301)

   c. Surgeon ID.....__ __ __ __ __ __ __ __

   d. Was ultrasound vascular mapping done before surgery? .....__

      (0=no, 1=yes, 9=unknown)

   e. Was patient on hemodialysis at time of fistula placement? (0=no, 1=yes) .....__

   f. If no, is the patient on hemodialysis now?.....__

3. Patient's dominant arm for eating (1= righthanded, 2= lefthanded) .....__

4. Type of fistula

   a. Position.....__

      1 = forearm 2 = upper arm

   b. Side (1= right, 2= left) .....__

c. Anastomosis .....__
   1 = radial artery - cephalic vein
   2 = ulnar artery - basilic vein
   3 = brachial artery – cephalic vein
   4 = basilic vein transposition
   5 = unknown
   6 = other (specify) _____

5. Previous access in the same arm? (0=no, 1=yes) .....__
   If YES,

   a. Type (1=fistula, 2=graft, 3=both, 4=unknown) .....__

   b. Position (1=forearm, 2=upper arm, 3=both) .....__

6. Previous access in the other arm? (0=no, 1=yes) .....__

7. Were any repairs / procedures done on the fistula since it was placed? (0=no, 1=yes) ....__

   Note: If there were repairs done, make sure a Access Repair / Access Event Procedure Form 352 was completed.

8. Did any events occur to the fistula since it was placed? (0=no, 1=yes).....__

   Note: If there were events, make sure a Access Repair / Access Event Procedure Form 352 was completed.

9. Was the fistula abandoned prior to this visit? (0=no, 1=yes).....__

   Note: If the fistula was identified as abandoned, Form 305 should not be completed.

For all patients for whom Q9 = No:

10. a. ID of Measurer 1.....__ __ __ __ __ __ __ __

    b. Bruit detectable along the vein at least 8 cm proximal to the arteriovenous anastomosis? (0=no, 1=yes).....__

    Note: Item 10b is used to determine the primary outcome of the study.

    c. Bruit detectable at the arteriovenous anastomosis? (0=no, 1=yes) .....__

    d. Thrill during systole? (0=no, 1=yes) .....__

    e. Thrill during diastole? (0=no, 1=yes).....__

    f. In your clinical judgment, will this fistula eventually be usable for dialysis? (0=no, 1=yes, 9=unknown).....__

For QC patients:

    g. ID of Measurer 2.....__ __ __ __ __ __ __ __

    h. Bruit detectable along the vein at least 8 cm proximal to the arteriovenous anastomosis? (0=no, 1=yes).....__

    i. In your clinical judgment, will this fistula eventually be usable for dialysis? (0=no, 1=yes, 9=unknown).....__

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For all patients:

11. Was a two-step basilic vein transposition lifting surgery planned? (0=no, 1=yes).....__

12. Were clamps ever used on this patient? (0=no, 1=yes) .....__

13. Was the patient taking his/her assigned DAC study drug for six weeks? (0 = no, 1 = yes, 11 = Pt died more than 6 weeks after randomization and there is no way we can know.)__

14. If no, approximate date when patient quit taking the drug ..... __ __ /__ __/__ __ __ __

    Note: If q.13 = no, make sure Form 335 or 336 is completed

15. Did the patient return his/her bottle? (0=no, 1=yes).....__

16. If yes, how many pills were in it?.....__ __

17. Which treatment group does the study team think this patient was randomized to?.....__

    1 = The team has been unblinded and knows it is placebo
    2 = The team believes this patient was randomized to placebo
    3 = The team does not know
    4 = The team believes this patient was randomized to active drug
    5 = The team has been unblinded and knows it is active drug

18. If Q17 = 1 or 5, Date of unblinding ..... __ __ /__ __/__ __ __ __

19. In retrospect, was there an appropriate fistula placement for a patient enrolled in the DAC fistula study? (0=no, 1=yes) .....__

20. If no, please explain _____

201. Date this form completed..... __ __/__ __/__ __ __ __

202. User ID of person completing this form .....__ __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered __ __/__ __/__ __ __ __

Person Entering this Form_____