Randomization Worksheet

AVID

When ready to randomize call:
1-800 253-1387 weekdays, 7am-5pm Pacific time
otherwise pager (206) 989-5212 [punch in your number (area code + phone number)]

Patient ID: ___-___-___ ___
seqnum05

1. **Today's date:** ___/___/___
days05
mo day yr

Patient's name: _____

Name of person placing call: _____ Code: ___

Name of person at CTC: _____ Code: ___

qldone05

2. **Is baseline Quality of Life form completed and in hand?** O Yes O No
1 0

If no, form not completed because (Check all that apply)
qlref05 O Patient refused
qlill05 O Patient is too ill to complete it
qlilit05 O Patient ~~doesn't read English~~ illiterate
qloth05 O Other
qlwork05 O Patient is working on form now

qlclbk05 If patient is working on form now, you will:
1 O Call back for the randomization after the form is completed and in hand
2 O Collect the QL form from the patient BEFORE telling the patient the assignment

3. **Randomizing hospital:** _____ Code: ___

Hospital where device would be implanted
(if randomized to ICD): _____ Code: ___

4. **Initiation of AVID Therapy**

If this patient is randomized to amiodarone, drug should be started within 1 day. If the patient is randomized to sotalol, either a Holter should be started within 1 day or baseline EPS scheduled within 3 days. If the patient is randomized to device, NTL implantation should be scheduled within 3 days and epicardial placement within 5 days.

Are you prepared to begin AVID therapy? strttx05
Cannot randomize unless prepared to begin.
O Yes O No
1 0

rtnum05

5. **Gender:** O Male O Female sex00 in CIR
1 0

6. **Race:** O White O Black race05: 0=white, 1=non-white
O Asian O Native American O Other

Hispanic origin: O Yes O No

7. **Age:** ⌊_⌋⌊_⌋ age00 in CIR

8. **Health Insurance:**
O Private insurance O HMO O VA/military
O Medicare/medicaid O None

9. **QL form preference:**
O English O Spanish
O Cannot participate
because: O Cannot read English or Spanish
O Vision or other physical limitation
O Refuses

10. **Index arrhythmia:** Date: ⌊_⌋⌊_⌋/⌊_⌋⌊_⌋/⌊_⌋⌊_⌋⌊_⌋⌊_⌋
mo day yr

arrtyp05 Type of event:
1 O (A) Primary cardiac arrest due to VF, *not* associated with new MI or transient or correctable cause
2 O (B) Documented sustained VT with syncope
3 O (C) Documented sustained VT with near syncope, systolic BP < 80 mmHg or chest pain AND EF ≤ 0.40

inhosp05 Location of event: O In-hospital O Emergency Room O Out-of-hospital
1 2 3

11. **Decision regarding revascularization**

Any decision regarding revascularization (includes CABG, PTCA, and atherectomy) must be made prior to randomization.
Has the decision regarding revascularization in this patient been made?

revdec05 ○ Yes (1) ○ No (0)

If "Yes", what was the decision?

revtyp05
1 ○ No revascularization
4 ○ Revascularization performed since index event
2 ○ Revascularization planned

If revascularization (CABG, PTCA, atherectomy) performed, what was the date:

__/__/__ dycabg05
mo day yr

If revascularization (CABG, PTCA, atherectomy) planned, what date is scheduled:

__/__/__ dyrev05
mo day yr

ef00 in CIR

12. **Ejection fraction:** 0.__ *Cannot randomize if >0.40 and arrhythmia (C) or revascularization planned.*

Date EF obtained: __/__/__ dyef05
mo day yr

13. **Has the patient had other open heart surgery since the index event?**

othsrg05 ○ Yes (1) ○ No (0)

If yes, date of surgery dysurg05 __/__/__
mo day yr

14. **Has signed informed consent been obtained?** infcon05 ○ Yes (1) ○ No (0)
Cannot randomize unless consent has been obtained.

15. **Are baseline forms and Registry form through item 10 complete?** ○ Yes (1) ○ No (0)
Cannot randomize unless forms are complete. blcomp05

16. **Are any exclusions checked?** exclus05 ○ Yes (1) ○ No (0)
Cannot randomize if ANY exclusions checked.

17. **Has the patient/patient's physician been advised regarding the use of aspirin, ACE inhibitors and beta-blockers?** mdadvu05 O Yes (1) O No (0)

18. **Has the patient/patient's physician been informed regarding the inadvisability of changing these medications during titration of study drug?** mdadvc05 O Yes (1) O No (0)

19. **Does the patient have a known contraindication to sotalol?** nosota05 O Yes (1) O No (0)

If yes, check all that apply:

asthma05 O Bronchial asthma
brady05 O Severe sinus bradycardia
avblok05 O 2-3° AV block
hxinef05 O History of clinical inefficacy
O Uncontrolled CHF chf05
O Hypersensitivity to sotalol hyprsn05
O Non-inducible or insufficient ectopy nonind05

invcon05 O Investigator concern
chfcon05 O CHF
efcon05 O Low EF
othcon05 O Other specify _____

20. **Have you approached the patient's spouse or partner to participate in the Quality of Life study?**

O Yes
O No
- O Intend to soon
- O Awaiting IRB approval for Spouse QL
- O Other reason: _____

O Not applicable (no spouse/partner)

21. **Randomization assignment:**

iddrg00, drgtyp00 in CIR

O Device
O Drug: O Amiodarone O Sotalol

22. **Method of cost utilization data collection:**

O None
O "Shoebox" (accordion folder)

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