

AFRICAN AMERICAN STUDY OF KIDNEY DISEASE
AASK STUDY

RANDOMIZATION CHECKLIST OR BASELINE DROP OUT FORM # 53

This form is completed for those who are eligible to continue on the basis of SV2 whether or not they will have a baseline GFR or go on to be randomized.

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1. Identification Number.....

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2. Name Code.....

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3. Date Patient Left or Completed Baseline: mm/dd/yy..... BL-ENDDT

4. What is the status of the patient? — BL-STH
0=Completed baseline through G2, didn't develop an exclusion, didn't drop out
1=Dropped out or excluded prior to G2
2=Dropped out or excluded after G2

5. Eligibility Issues — — BL-EL
0=Completed Baseline through G2, didn't develop an exclusion, didn't drop out

- 1=The patient developed some exclusion listed in Items 6-37
- The patient dropped out or refused to consent primarily due to:
- 2=Patient preference: unable to arrange care for dependents
- 3=Patient preference: conflict with personal schedule
- 4=Patient preference: conflict with work schedule
- 5=Patient preference: transportation problems
- 6=Patient preference: did not like the clinic visits
- 7=Patient preference: did not like or did not want GFR tests
- 8=Patient does not want to do back titration of medications
- 9=Patient does not want to be randomized in principle
- 10=Patient does not want to be randomized to blood pressure level
- 11=Patient does not want to be randomized to medication regimen
- 12=Patient preference: unwilling to meet all demands of study
- 13=Patient preference: does not believe participation will be beneficial
- 14=Patient preference: lack of support from family and/or others
- 15=Patient preference, reason unknown
- 16=Patient preference, other reason, specify (not key entered _____)
- 17=Patient moved out of service area

PATIENT

- 18=Personal physician preference
- 19=Study team preference
- 20=Serum potassium >5.5 mg/dl at both SV2 and G1
- 21=WBC <2500/mm³ at both SV2 and G1 (Leukopenia)
- 22=G1 out-of-range
- 23=>24 weeks since SV2 if no G2, or >8 weeks since G2
- 24=Could not meet blood pressure back titration criteria
- 25=Serum Creatinine result made the team not want to do a GFR
- 26=Serum Glucose >200 mg/dl at either SV2 or G1
- 27=Fasting Serum Glucose >140 mg/dl on two occasions
- 28=Protein creatinine ratio >2.5
- 29=Age <18 years or >70 years
- 30=GFR CV >50% on two occasions

If any exclusion criteria were found, document by answering
1=Yes to any that apply. The others may be left blank. If none were found, skip to 200.

ELIGIBILITY

- 6. Has the patient ever had kidney dialysis PREVDII
- 7. Has participant ever received a kidney transplant RENAL
- 8. History of diabetes mellitus I or II Dm_HX
- 9. Undisputed medically indicated need for nonsteroidal anti-inflammatory agents (NSAIDs) \geq 15 days/month, excluding aspirin NSAID
- 10. Medically indicated need for ACE inhibitor for reasons other than hypertension ACE
- 11. Medically indicated need for beta blocker for reasons other than hypertension BB
- 12. Medically indicated need for calcium channel blocker for reasons other than hypertension CCB
- 13. History of serious adverse reaction to ACE inhibitor ACE-REA
- 14. History of serious adverse reaction to beta blocker BB-REA
- 15. History of serious adverse reaction to calcium channel blocker CCB-REA
- 16. Malignant or accelerated hypertension within the last six months HTN
- 17. Known secondary cause of hypertension (such as renal vascular hypertension or endocrine hypertension) HTN2
- 18. Clinical or biopsy evidence of any other renal disease other than hypertensive nephrosclerosis RENAL DIS
- 19. Patient has HIV/AIDS HIV/AIDS
- 20. Patient has other serious systemic disease (including cancer) that might influence survival (specify disease: _____) SSD2
- 21. Patient has serious systemic disease that might influence the course of renal disease but does not influence survival (specify disease: _____) SSD2
- 22. Current or recent (within 6 months) evidence of congestive heart failure; documentation of ejection fraction $<$ 35%; or heart block $>$ first degree CHF

NOTE: For Eligibility & CERTIFICATION tables,
VIST = Bx, VISA = 3, VISSEQ = 0

ELIGIBILITY

- 23. Serum potassium > 5.5 mEq/L confirmed by repeated measurements within the past year (for participants not on potassium supplements) (1=yes, 2=no, 9=unknown) SPOTASS
- 24. Laboratory evidence of nephrotic range proteinuria > 3.5 g/day PROTEIN
- 25. To confirm item 13 on Form 2
Female who is pregnant or planning to become pregnant during the next 5 years? (0=no, 1=yes, 9=not applicable) PLANPR
- 26. Drinks more than 21 drinks of wine, beer or alcohol during an average week in the last two years? (0=no, 1=yes) ALCOHO
- 27. Treated for asthma for over 2 continuous weeks in the last 6 months? (0=no, 1=yes) ASTHMA
- 28. Participating in any other health studies that involve an active intervention and would exclude the patient from this study? (0=no, 1=yes) OTH-STD
If yes, specify: _____
(not key entered)
- 29. Planning to move more than 50 miles from this area in the next five years? (0=no, 1=yes) MOVING
- 30. Difficulty emptying bladder? VOIDING
- 31. Allergic to iodine IODINE
- 32. Likely not to be able to adhere to medications MEDS_A
- 33. Likely not to be able to follow the visit schedule SCHED-AD
- 34. Possible drug abuse problem DRUGS
- 35. Obesity (2=yes, arm size > 41 cm and ≤ 52 cm, and arm is too short for thigh cuff, 3=yes, arm size > 52 cm) OBESITY
- 36. Leukopenia LEUKOPEN
- 37. Is this patient ineligible due to some reason not shown in questions 6-36? OTH-EXCL
- 38. Does the participant appear to be eligible? (0=not eligible, 1=eligible) ELIG

CERTIFICATION

- 200. Date this form completed ___/___/___
- 201. Certification ID of person completing this form COMPL-BY
- 202. Certification ID of person entering this form ENTER-B

For Clinical Center Use Only

Date Entered ___/___/___ Verified? _____