

Procedures at combined Screening/Baseline visit

Written informed consent

Vital signs, including waist circumference

Confirm that participant meets BMI and blood pressure eligibility criteria before proceeding

Medical history

Confirm that participant meets eligibility criteria before proceeding

Medication and supplement review

Confirm that participant is not taking any excluded medications (see MOP 8, section 8.4)

Physical Exam (may be done at the randomization visit, prior to randomization in SPIRS).

Fasting laboratory specimen collection (MOP 9, section 9.7.3 and appendix 7)

- Urine pregnancy test (if female of reproductive potential)
- CBC without differential*
- LFTs (ALT, AST)*
- Serum calcium*
- Serum creatinine*
- Baseline tubes for the Central Laboratory

*Do not need to be repeated, if completed within the past 6 weeks and meet the following criteria:

- ✓ Blood samples were obtained via phlebotomy (i.e., not a finger-stick).
- ✓ The glucose (plasma or serum) drawn outside of D2d was done while fasting >8 hours overnight.
- ✓ The laboratory tests were run at the same local laboratory used for D2d.

Send specimens for local analysis to local laboratory and begin processing specimens for the Central Laboratory

Begin questionnaires (FFQ, IPAQ)

30 minute laboratory specimen collection (MOP 9, section 9.7.3 and appendix 7)

120 minute laboratory specimen collection (MOP 9, section 9.7.3 and appendix 7)