

**MOST Ancillary Study (AS14-06) D. Felson, D. Misra
“Fat and Osteoarthritis – pilot study”**

TABLE OF CONTENTS

1. Dataset description and Analyst Notes	2
2. Selection plan.....	3
3. Membrane Sciences Laboratory – FFA assays.	4
4. Univ. of Vermont Laboratory – assays:	4

1. Dataset description and Analyst Notes

Dataset: AS1406pilot_bioassay.sas7bdat

Observations: 150 records (150 participants, 16 assays, case/control study)

Documentation:

- VariableGuide_ AS1406pilot_bioassay.pdf
 - Distributions_ AS1406pilot_bioassay.pdf
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AS1406pilot_bioassay dataset contains 150 records (one record per participant) with assays results (total FFAs and also levels of individual FFAs including saturated and unsaturated FFAs) performed in the Membrane Sciences Laboratory (San Diego) and seven anti-inflammation assays performed at the University of Vermont Laboratory for Clinical Biochemistry Research on baseline serum. This was a pilot study and intended to run assay on all eligible participants, however the main study was not funded.

Note, for this study, both laboratories were blinded to clinical data (case/control selection) and demographic characteristics of the participants.

ANALYST NOTES:

- Case/control selection indicator included in the dataset (variable #31 case).
- Variables #5 to #24 are provided by the Membrane Science laboratory and include the average value from 3 trials and CV value for each analyte.
- Variables #25 to #30 are provided by the University of Vermont Laboratory for Clinical Biochemistry Research
- When assay results were not obtained, special missing value were used:
 - .L = below low detection level
 - .H = above high detection levelValues .L and .H can be used in categorical analysis only. Alternatively, the analyst can assign the special value above detection or below detection if requested by investigator.
- If there was insufficient volume or some other reason assay could not be performed, and all assay values were missing, the record is not included in the analytical dataset.

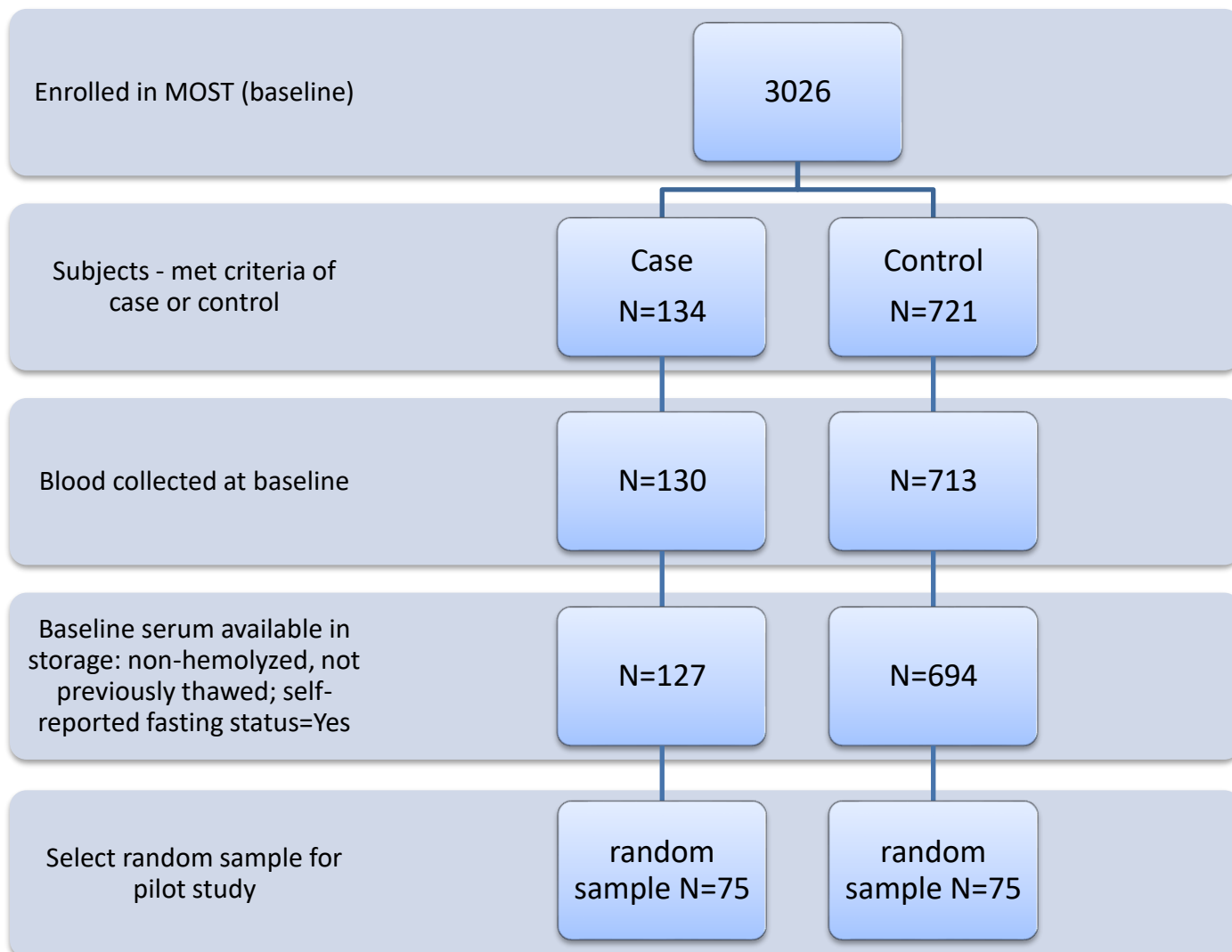
2. Selection plan

Enrolled in MOST: N=3026 subjects

Cases – subjects with ROA incidence between baseline and 30 m clinic visit (x-ray readings)

Controls – subjects without OA as of 84m clinic visit on both knees (x-ray readings).

Figure 1 – FLOW chart for Pilot study selection.



Aliquots of serum (400 uL each) from the baseline MOST examination provided to University of Vermont laboratories and the Membrane Sciences Laboratory where they were thawed and analyzed for selected assays.

3. Membrane Sciences Laboratory – FFA assays.

The Membrane Sciences Laboratory provided data on total FFAs and also levels of individual FFAs including saturated and unsaturated FAs. The coefficient of variation for the assay for unbound free fatty acids in the Membrane Sciences Laboratory, which introduced and developed this assay, is 6.5%.

4. Univ. of Vermont Laboratory – assays:

To study the relation of the following pro- and anti-inflammatory adipokines to OA phenotypes: pro-inflammatory – leptin, soluble leptin receptor, visfatin, IL-6, TNF α , and serum amyloid A (SAA); anti-inflammatory – high molecular weight (HMW) adiponectin - assays listed below.

Table 1. Assays performed in UVM.

Analyte	Assay	Inter-assay CV
Leptin	R&D Systems ELISA	7.6-13.1%
sLeptin Receptor	R&D Systems ELISA	5.3-8.6%
HMW Adiponectin	Millipore Elisa	6.7-8.6%
Visfatin	Biovendor Elisa	5.5-9.1%
TNF α	R&D Systems ELISA	7.6-12.8%
IL-6	R&D Systems ELISA	8.3-12.8%
SAA	Siemens BNII Nephelometer	3.7-8.8%