SWANRep052_NELA

SWAN Repository Dataset Documentation

Study: App 052, "The relationship between daily urinary reproductive hormone levels and mood symptoms during the menopausal transition", Lasley
Datasets: SWANRep052_NELA
Cohort: SWAN DHS

Summary, PdG from DHS-H1 NELAs, Repository Protocol #052

1. **Who is included in the dataset?**
   A subset of 46 participants from the 148 DHS participants who were in the CC-frozen DHS datasets at the H1 visit and were classified as no evidence of luteal activity (NELA) using the Kassam algorithm. The dataset includes PdG and creatinine measurements for 1383 days of collection from these 46 collections/participants.

   All 46 participants were classified as "NELA bleed with E1C rise" group – that is, they were classified as NELA, their collection ended due to menstrual bleeding, and E1c values demonstrated a rise as defined in Weiss G, Skurnick JH, Goldsmith LT, Santoro NF, Park SJ. Menopause and hypothalamic-pituitary sensitivity to estrogen. JAMA 2004;292;2991-2996. Briefly, an E1c rise was defined as "an E1c level of at least (1) 50 pg/mg creatinine, (2) twice the baseline level (the mean of 5 consecutive days starting 9 days earlier), and (3) 3 standard deviations of the baseline levels above the baseline mean. In addition, the estrogen peak was required to culminate in a drop to no more than 1.5 times baseline at some time within the next 5 days." (Weiss et al., 2004)

   Upon review of the data and profiles, it was determined that: 1) the new PdG profiles were consistent with those obtained from the original CLASS data although levels were lower which was expected as samples were 15+ years old and 2) evidence of some luteal activity was present in many of the intervals (from all NELA categories, not just those collections ending with bleeding or demonstrating an E1c rise) based on the collective evaluation of E1C, PdG, FSH and LH together.

2. **Language and translation**
   There were no issues regarding language and translation.

3. **Included variables**

Variable name	Description of the variable	Codes
ARCHID	Encrypted SWAN Subject ID	
VISIT	DHS study visit	H1
DATE_COLLECTED	Date of daily urine collection	
CREATININE_MG_ML	Creatinine (mg/mL)	
PDG_UG_ML	PdG (ug/mL)	
PDG_UG_ML_CR	Creatinine-corrected PdG = PDG_UG_ML / CREATNINE_MG_ML (ug/mg Cr)	

4. **Description of PdG assay**

The PdG is a competitive chemiluminescent immunoassay utilizing a polyclonal PdG antibody and a conjugate of PdG labeled with horseradish peroxidase and dimethyl acridinium ester. The PdG in the unknown sample competes with the labeled PdG conjugate for a fixed number of binding sites. Goat anti-rabbit IgG covalently bound to paramagnetic particles is added for separation of bound and unbound components. Acid and base reagents initiate the chemiluminescent reaction and the intensity of the reaction is measured in relative light units (RLUs). An inverse relationship exists between the amount of PdG present in the unknowns and the relative light units detected. All samples were initially analyzed at a dilution 1:10 and reanalyzed at 1:50 if necessary. Intra-assay CV was 2.1% and inter-assay CV was 3.9%.