SAP

Measurement of Agricultural and Dietary Glyphosate Exposure among Pregnant Women

NCT04155463

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Target journal: Environmental Health Perspectives

Study Design: Randomized cross-over trial

Research objective: Examine differences in specific gravity-standardized urinary glyphosate levels between a one-week conventional diet and one-week organic diet among 40 pregnant women

Hypothesis: Urinary glyphosate levels will be significantly lower during the one week in participants consumed organic diets, compared to the one week in which they consumed their normal conventional diet. Reductions will be even greater among participants living > 0.5 km from agricultural fields.

Statistical Analysis Plan:

1. Calculate the average glyphosate concentration from the two sets of seven individual daily samples that were analyzed and confirm that the average is the same as the value from the composite sample for that participant
2. Calculate detection frequencies and examine normality of the data
3. Impute any values <LOD as $\frac{LLLLLL}{\sqrt{2}}$
4. Adjust urinary values for specific gravity, based on Chiu et al. 2018, $C_{SG} = C^*[(Avg_{SG} - 1) / (Ind_{SG}-1)]$ where Avg_{SG} is the average specific gravity measured in the cohort as a whole and Ind_{SG} is the specific gravity of the individual sample being adjusted.
5. If the data are non-normally distributed, run two-tailed Wilcoxon sign rank test to assess difference in urinary glyphosate levels between the conventional and organic diet weeks. If the data are normally distributed, run two-tailed paired t-tests for this comparison.
    - *a.* Primary analysis:
        - i. All 39 individuals
    - *b.* Secondary analyses:
        - i. Exclude participants missing $\geq$ 4 samples from either week
        - ii. Exclude participants who didn't turn in food diaries
        - iii. Exclude participants who didn't write anything for food consumed from outside of study
        - iv. Exclude participants who had a Likert scale <22 (include imputing "0" for any "N/As" from each day)
        - v. Exclude participants who scored <36 on writing foods down
        - vi. Additional combinations of the above exclusions may be explored
    - *c.* Stratified analysis:
        - i. Evaluate the above comparison separately among those living $\leq$ 0.5 km from an agricultural field vs. > 0.5 km from an agricultural field