

DNTP Studies at the NIEHS Clinical Research Center

1. Bisphenol A (BPA) Pharmacokinetic (PK): Controlled Exposure Study

Study Design: A single arm, two-period pharmacokinetic study involving the administration of deuterated bisphenol A (d-BPA) as either a single oral dose and/or as a single dermal application, both at 100 µg/kg bw of d-BPA.

Primary Objective: The primary objective of this study is to measure an increase in d-BPA and d-BPA glucuronide and sulfate in blood and urine after administration of an oral and/or a single dermal dose of 100 µg/kg bw of d-BPA and to monitor the decline of these two compounds in blood and urine over a 3-day period after each dose.

Primary Endpoint: The primary endpoints are key pharmacokinetic measurements of d-BPA and d-BPA conjugates in blood and urine over 3 days after a single dose of oral and/or dermal administration of a dose of 100 µg/kg bw of d-BPA.

2. BPA Biomonitoring Study in Cashiers

Study Design: Measure differences in serum and urine levels of BPA and conjugates pre and post shift in individuals working as cashiers using thermal receipt paper containing BPA or bisphenol S.

Primary Objective: The primary objective of this study is to determine whether current analytical methods are sufficiently sensitive to monitor changes in BPA, BPS or conjugate levels in people handling thermal register tapes containing BPA or BPS.

Primary Endpoint: The primary endpoints are to obtain estimates of the range of dermal absorption of BPA or BPS from register tapes during the course of a work shift.

3. Remifemin- Black Cohosh Exposure Study

- Study Design:** Recruit women who already use Remifemin brand black cohosh herbal supplement, and age and race matched controls. Draw bloods for micronucleus determination and other endpoints.
- Primary Objective:** The primary objective of this study is to evaluate an indication of chromosomal damage following at least 3 months of daily use of a black cohosh-containing herbal product.
- Primary Endpoints:** The primary endpoint of this study is measurement of the frequency of micronucleated immature erythrocytes (reticulocytes) in peripheral blood of women who are taking an herbal product containing black cohosh. Additional endpoints that were selected to measure factors associated with anemia include hematocrit, CBC, folate levels, and cobalamin levels.