

ESC Virtual Seminar

Estetrol: a significant innovation in contraception

Questions & answers by **Mitchell D. Creinin, USA**

- **Can we give this pill in treatment with antiepileptic drugs without aletraio of efficacy?**
Drospirenone is still metabolized through the CYP3A system so any antiepileptic that induces liver enzymes would still impact the E\$/DRSP pill.
When phase3 clinical studies, was E4 given daily as other contraceptive pills?
Once daily, 24/4 regimen.
- **Noted quite a big drop out from the phase 2 study of E4/DRSP with 9% and 18% in the groups, respectively. Were these due to bleeding or other reasons?**
Two persons in EE/DRSP had mood issues and one person in E4/DRSP had mood issues. All others were protocol violations or non-AE study related reasons. Phase 2 studies have high demands and the d/c subjects otherwise did not discontinue for AEs.
- **Can we give pliils with estetrol to women on anyiepli?**
Remember that DRSP is still metabolized by Cyt P450 so it is not considered any different than other COCs when a woman is using an antiepileptic that impacts the Cyt P450 system.
- **What about E4/dsp - effect on mood? Risk of depression?**
In neither phase 3 study did depression pass the 2% threshold for reporting rates. Thus, the rates in both studies were less than 2%. D/C for mood changes in Europe/Russia was about 1% and in US/CA was <0.5%.
- **From what plant source is E4 synthetized?**
Soy - same as other hormones today.
- **Cyt P450 inducers will decrease the efficacy of DRSP, I presume?**
Yes
- **Is there any contra-indication in case of migraine?**
We have no current evidence that E4 is safer in persons with migraines with aura than other estrogens. More data will be needed.
- **Could it be administerd to patients with trombophila but without tromboembolia?**
Estrogens, including E4, are contraindicated in persons with thromboembolic
- **What about the use of E4 for AVV? I mean atrophy of menopausal mucosa?**
Has excellent activity in very low doses on the vaginal mucosa...HT is coming!!
- **E4 and impact on sexual desire?**
Quality of life studies demonstrated no change or slight improvement for those scores. However, like anyone using DRSP, there is a slight chance of reporting such a change.