# DHEA Research Abstracts

## Improvement in Mood and Fatigue after Dehydroepiandrosterone Replacement in Addison's Disease in a Randomized, Double Blind Trial.

***Hunt PJ, Gurnell EM, Huppert FA et al.***
***The Journal of Clinical Endocrinology & Metabolism. 2000 Dec; 85(12): 4650-6***

This randomised, double blind study involved 39 patients with Addison's disease who were randomised to receive either 50mg oral dehydroepiandrosterone (DHEA) daily for 12 weeks followed by a 4-week washout period and then 12 weeks of placebo, or vice versa. Prior to receiving treatment, the patients with Addison's disease had markedly subnormal DHEA-sulphate (DHEA-S) and DHEA levels. This study found that 50mg of DHEA corrected this deficiency, elevating the mean circulating DHEA-S level to 4.93 µmol/L. The rise in DHEA-S was also associated with the normalisation of its metabolite, Δ4-androstenedione and salivary levels of DHEA. In addition to its biochemical effectiveness in Addison's disease, oral DHEA was well tolerated by the study participants and was associated with an improvement in psychological well-being, mood and fatigue.

## Intravaginal dehydroepiandrosterone (Prasterone), a physiological and highly efficient treatment of vaginal atrophy.

***Labrie F, Archer D, Bouchard C, et al.***
***Menopause. 2009 Sep-Oct; 16(5):907-22***

This prospective, randomised double-blind and placebo-controlled phase III clinical trial involved 216 post-menopausal women. The aim was to study the effect of DHEA when administered vaginally on the signs and symptoms of vaginal atrophy. The researchers found that all three daily doses of DHEA (0.25%, 0.5%, and 1.0%) resulted in significant and beneficial changes in the percentage of vaginal parabasal and superficial cells, pH and symptoms at two weeks and again at 12 weeks. The study concluded that the administration of DHEA resulted in rapid and efficient reversal of the symptoms and signs of vaginal atrophy with either no or minimal changes in the levels of steroid in serum.

## Long-term administration of intravaginal dehydroepiandrosterone on regression of low-grade cervical dysplasia - a pilot study.

***Suh-Burgmann E, Sivret J, Duska LR, Del Carmen M, Seiden MV.***
***Gynecologic and Obstetric Investigation. 2003; 55(1): 25-31.***

This pilot study looked to determine the efficacy and safety of intravaginal DHEA in a group of 12 female patients with low-grade cervical dysplasia. DHEA was administered as a 150mg daily dose for a period of up to 6 months. Cervical follow-up evaluations were carried out at 3 and 6 months from starting the DHEA treatment. At the end of the study 83% of the women were found to have no evidence of dysplasia and no serious side effects were reported. Overall, the researchers concluded that intravaginal DHEA was safe and well tolerated by all participants of the study, and that use of DHEA may promote regression of low-grade cervical lesions.

## Effect of 12-month dehydroepiandrosterone replacement therapy on bone, vagina, and endometrium in postmenopausal women.

***Labrie F, Diamond P, Cusan L, et al.***
***The Journal of Clinical Endocrinology and Metabolism. 1997 Oct; 85(10): 3498-3505.***

This study aimed to determine the effect of DHEA replacement therapy over a period of 12 months in a group of 14 post-menopausal women between the age of 60-70. The women received daily application of 10% DHEA cream. The study found that there was vaginal epithelium maturation in 8 out of 10 women who had a maturation value of zero at the onset of replacement therapy. Furthermore, the estrogenic effect of DHEA observed in the vagina was not observed in the endometrium which remained atrophic in all women. Another finding

of the study was that the bone mineral density (BMD) significantly increased at the hip after the 12-month treatment period, thus emphasising the benefits of DHEA replacement therapy.

**High internal consistency and efficacy of intravaginal DHEA for vaginal atrophy.**
***Labrie F, Archer D, Bouchard C, et al.***
***Gynecological Endrocrinology. 2010 Jul; 26(7): 524-32***
This study analysed data obtained from a phase III clinical trial involving 218 post-menopausal women with vaginal atrophy who received daily intravaginal DHEA (0.25%, 0.5% or 1.0%) for a 12-week period. One of the main findings was that the 0.5% DHEA daily intravaginal dose was found to have a 'statistically significant' to 'highly significant' effect on all parameters of vaginal atrophy. It was also found to not significantly affect the serum levels of estrogens, further emphasising its clinical effectiveness.

**Dehydroepiandrosterone treatment of women with mild-to-moderate systemic lupus erythematosus: a multicentre randomized, double-blind, placebo-controlled trial.**
***Chang DM, Lan JL, Lin HY, Luo SF.***
***Arthritis and Rheumatism. 2002 Nov; 46(11): 2924-7.***
This aim of this study was to evaluate the efficacy and tolerability of a daily dose of 200mg DHEA versus a placebo in 120 women with active systemic lupus erythematosus (SLE). The researchers found that the number of patients with flares decreased by 16% in the group receiving DHEA. In addition, the number of women with serious adverse events, most relating to SLE flares, was significantly lower in the DHEA treated group compared with the placebo group.

**Effect of dehydroepiandrosterone supplementation on bone mineral density, bone markers, and body composition in older adults. The Dawn Trial.**
***Von Mühlen D, Laughlin GA, Kritz-Silverstein D, Bergstrom J, Bettencourt R.***
***Osteoporosis Inernational. 2008;19(5): 699-707.***
The aim of this randomised, placebo-controlled trail was to examine the effect of a daily dose of 50mg oral DHEA on the bone mineral density (BMD), bone metabolism and body composition in healthy adults aged between 55 and 85 years. The supplementation period lasted a year and they found that DHEA supplementation increased both serum DHEA and DHEA-sulphate levels to the concentrations measured in young adults 3 months into the study. Specifically, there was a positive effect of the supplementation on both lumbar spine BMD and C-terminal telopeptide (CTx) levels in the female group.

**Serum levels of sex steroids and metabolites following 12 weeks of intravaginal 0.50% DHEA administration.**
***Ke Y, Labrie F, Gonthier R, et al.***
***The Journal of Steroid Biochemistry and Molecular Biology. 2015 Nov; 154: 186-96***
The aim of this study was to assess the efficacy of daily intravaginal administration of 0.50% DHEA for a 12-week period, on moderate to severe dyspareunia in post-menopausal women with vulvovaginal atrophy. After 12 weeks of treatment, 11 serum sex steroids levels were measured, and the researchers found that they all remained within the normal post-menopausal values. Specifically, serum estradiol was found to be around 22% below average normal post-menopausal values. This finding confirms that there is intracellular transformation of DHEA in the vagina resulting in local efficacy.

**The safety of 52 weeks of oral DHEA therapy for postmenopausal women.**

***Panjari M, Bell RJ, Jane F, et al.***

***Maturitas. 2009 Jul; 63(3): 240-245.***

This study aimed to evaluate the safety of DHEA for post-menopausal women. The women in the study were randomised to receive a daily dose of 50mg oral DHEA or a placebo. Over 52 weeks, the effects of DHEA versus the placebo on lipid profile, insulin-glucose homeostasis and the endometrium were studied. Overall, the study found that the administration of 50mg DHEA daily did not significantly affect the lipid profile, insulin sensitivity or the endometrium.

**Update on the use of dehydroepiandrosterone supplementation among women with diminished ovarian function.**

***Barad D, Brill H, Gleicher N.***

***Journal of Assisted Reproduction and Genetics. 2007 Dec; 24(12): 629-634***

The aim of this case control study was to assess the effect of DHEA supplementation on pregnancy rates in a group of women with diminished ovarian function. There were 89 patients in the study group who received 75mg of oral, micronised DHEA daily for a period of up to 4 months prior to in vitro fertilisation. The control group consisted of 101 couples who received infertility treatment but no DHEA supplementation. Overall, the study found that there was a significantly higher cumulative pregnancy rate in the group receiving DHEA treatment, thus supporting the use of DHEA among women with diminished ovarian function.