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MANAGEMENT OF ENDOMETRIAL POLYPS IN MENOPAUSE PATIENTS UNDER HRT

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45 menopause patients developed irregular bleeding and an increase in endometrial thickness between 6 and 24 months after initiation of HRT. The regimens of HRT were Regimen A - estradiol subdermal implant + nomegestrol acetate implant [N=20], Regimen B - Transdermal estradiol + oral medroxyprogesterone (Wyeth) [N=17], Regimen C Sequential conjugated estrogens (Wyeth) + oral medroxyprogesterone [N=5], Regimen D - Continuous conjugated estrogens with medroxy-progesterone [N=3]. The mean endometrial thickness was 11 mm. A diagnostic hysteroscopy was carried out in all patients followed by endometrial suction. Hysteroscopy revealed the presence of endometrial polyps in all these patients. However, this diagnosis was missed by curetage in 42 out of 45 patients. Hystopathologic examination of endometrium removed by the karman curete revealed atrophy in 40 patients, proliferative endometrium in 2 and polyps in 3 patients. Thirty patients had their polyp removed with the 27F resectoscope. Hystopathological examination of excised polyp revealed cystic hyperplasia in 22 patients and adenomatous hyperplasia without atypia in 8 patients. TVS perfomed 6 months following the procedure revealed an endometrial echo less than 4 mm in 28 patients. Hysteroscopy revealed in 10 patients an uterine cavity with synechia.

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SUMMARY OF COMBINED DATA ON ENDOMETRIAL SAFETY CONSIDERING THE ENPOINT HYPERPLASIA IN POSTMENOPAUSAL WOMEN TAKING SEQUENTIAL, COMBINED ESTRADIOL AND DYDROGESTERONE (FEMOSTON)

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Four studies with Femoston® 2/10 (2mg micronised estradiol daily, sequentially combined in one tablet with 10mg dydrogesterone for 14 days per 28 day cycle), evaluating the endometrial safety, by means of endometrial biopsies, were pooled for statistical analysis. Two were double-blind, 6-month, dose-ranging studies and 2 were open, long-term (one up to two years) studies. All histological assessments were evaluated by independent central pathologists using criteria defined by pathologist Prof. H. Fox. Statistical analysis was done by a visit-wise analysis after 6, 12 and 24-months of treatment and by an intent-to-treat analysis. The endometrial safety data were combined, resulting in 369 patients treated with Femoston 2/1 0. In 256 patients treated for one year or more, one simple hyperplasia was diagnosed (failure rate - 0.39%, upper 95% confidence limit - 1.84%). The intent-to-treat analysis reported 369 patients with one simple hyperplasia (failure rate - 0.27%, upper 95% confidence limit - 1.28%). These results are in line with those reported in recent literature. We conclude that the endometrial safety of Femoston 2/10 is very good.

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BLEEDING PATTERN IN HRT REGIMENS WITH CONTINUOUS ESTRADIOL VALERATE (EV) AND SEQUENTIAL CHLORMADINONE ACETATE (CMA)

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Due to its antiandrogenic properties CMA has special importance for the development of new regimens for HRT. So, a phase III clinical trial including 187 postmenopausal women was made to test different doses of CMA (0.5, 1, 2 and 3 mg) for 12 days per cycle in combination with continuous EV (2 mg). Dose finding for CMA was based primarily on the bleeding patterns during the four treatment cycles and the histological evaluation of final endometrial biopsies (not reported here). A total of 69.5% of all patients had regular withdrawal bleeds during the study, whereas this value was highest (80.4%) in the 2 mg group. Unexpectedly, withdrawal bleeding was more intense and longer in the highest dose group. There was a shift towards a later start of bleeding with increasing dosage of CMA. The frequency of unclear bleeding was higher in the 0.5 mg (15.2%) and 3 mg (19.6%) , as compared with the 1 mg (10.2%) and 2 mg (10.9%) groups. Due to the fact that a regular bleeding pattern is considered to be essential for acceptability of sequential regimens for HRT, 2 mg of CMA was selected as the optimal dose for combination with 2 mg of EV.

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CONTINUOUS PREMARIN AND MEDROXYPROGESTERONE ACETATE VS TIBOLONE (LIVIAL): A COMPARATIVE STUDY OF EFFECTS ON CARBOHYDRATE METABOLISM, SAFETY, AND ACCEPTABILITY - AN INTERIM REPORT.

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The aims of this study were to compare the effect on carbohydrate metabolism, vasomotor symptoms, bleeding patterns and endometrial safety of two regimens of daily continuous oral administration of conjugated equine oestrogens (Premarin) and medroxyprogesterone acetate (MPA) and continuous Tibolone (Livial).
The study was an open, randomised, comparative parallel group multinational outpatient study. Eligible subjects were healthy postmenopausal women aged between 45-65 years inclusive, with post menopausal vasomotor symptoms and at least 12 months since last spontaneous menstrual period.

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