CLINICAL TRIAL STUDIES (As Principal or Co-investigator) 1989 - 2001

1. Open label study of continuous oestrogen and progesterone (oestradiol valerate 2mg and norethisterone 0.7mg) single centre study. 206 patients between 1991 and 1994. Climesse marketed 1996. Principal investigator. Objective: no bleed hormone replacement. (Novartis) See refs 44, 45, 48.

2. Open label study daily oestrogen and quarterly progesterone using oestradiol valerate 2mg and levonorgestrol 75ug called Nuvelle 3. 120 patients single centre between 1993-1995. Objective: quarterly bleed hormone replacement. Co-investigator. Study completed. Outcome: endometrial abnormalities, not marketed. (Schering).

3. Open label study with continuous oestrogen and progesterone using ^{17}beta-oestradiol 2mg and norethisterone acetate lmg called Primelle. 150 patients, multi-centre study 1994-1995. Co-investigator. Objective: no bleed hormone replacement. Completed study, - marketed, (Schering) Nuvelle continuous.

4. Open label study, continuous oral oestrogen ^{17}beta-oestradiol and quarterly progesterone norethisterone acetate lmg called Tribeta. 225 patients 1995-1998. Single centre study. Co-investigator. Objective: quarterly bleed HRT. Study completed: outcome unknown. (Schering).

5. Open label randomised multi-centre study. Progestasert (intra-uterine device) vs norethisterone orally 1 mg with oral ^{17}beta-oestradiol 2mg continuously to all patients. 228 patients. Co-investigator. A no bleed HRT study but discontinued half way through due to unacceptable bleeding patterns. (Astra Zeneca).

6. Open randomised dose-ranging comparator control parallel group study. Comparing test drug ^{17}beta-oestradiol lmg with natural progesterone 25mg or 50mg (Scheresol) against Premique 0.625mg of conjugated equine oestrogen and 5mg medroxyprogesterone acetate. No bleed HRT. 150 patients. Co-investigator. Study completed. Outcome: not marketed. (Wyeth).

7. Six month open label comparative study of two 7 day patches (Cygnus 13.5 and 27 cm2) vs Climara (12.5cm2) in postmenopausal women - symptoms and endometrial histology. Multi-centre study. 420 patients. Co-investigator. Study completed. Outcome: not known. (Wyeth).

8. Double-blind multi-centre randomised comparator controlled trial in postmenopausal women to investigate effect of intra vaginal ring device releasing ^{17}beta-oestradiol compared to oral oestradiol on symptoms of lipid metabolism and BMD. 132 patients. Principal investigator at Endocrine Centre and currently continuing. Completed February 2000. Marketed as Menoring 50, July 2001. (Galen). See refs 46, 47.

9. Phase II multi-centre double-blind placebo controlled parallel group study to observe a topical product (P45 cream) on treatment of alopecia androgenetica. Investigator for Blossom Inn Medical Centre on behalf of the Endocrine Centre. 70 patients. Current trial. Completed September 2000. Outcome - further trial.