Effects of continuous versus cyclical oral contraception: a randomized controlled trial.

There is continuing interest in the use of long-cycle and combined hormonal contraceptive regimens to improve premenstrual and menstrual ill-health. This paper is a well-designed, randomised, double-blind trial involving a total of 62 healthy women taking either combined pills for 21 days plus 7 days of placebo over six cycles or continuous therapy for 168 days.

It was surprising to see that a 20 µg ethinylestradiol and 1 mg norethindrone acetate pill was chosen for this study. The authors explained that previously published work had reported more days of amenorrhea and fewer days of spotting with such a preparation.

The subjects were studied for three menstrual cycles prior to enrolment. No hormonal contraception was taken during this time. They were then seen regularly during the ‘active’ phase of the study.

The women under 20% of women dropped out once taking the study medication with approximately half giving ‘uncomfortable with the side effects’ as their overall reason for discontinuing with the continuous pill for 21 days plus 7 days of placebo over six cycles or continuous therapy for 168 days.

Of the adverse events reported, those that were most likely to be attributed to the implant included headache (15.5%), weight gain (12.0%), acne (11.8%), breast pain (10.2%), emotional lability, depression and weight gain (5.2%). Complications from implant insertion and removal were reported.

Due to the progestogen content of the implant, bleeding irregularities were expected and occurred with no particular pattern. Comparisons between the bleeding patterns of patients using Norplant® and Implanon were made, and showed Implanon to cause fewer bleeding and spotting days and more amenorrhea. However, the statistical significance of these findings is limited by the small number of subjects involved in this part of the analysis.

Interestingly, geographical differences were noted when considering reasons for discontinuation. In the North American and European populations, bleeding irregularities were considered much less acceptable, contributing to 14% of premature removals of the implant, compared to only 4% in Southeast Asia, Chile and Russia. Side effects that were reported as reasons for discontinuation more frequently also showed regional differences with symptoms such as emotional lability, depression and weight gain more commonly cited by North American patients.

This report highlights the contraceptive effectiveness of Implanon and its general tolerability; however, the geographical variation in results must be considered when counselling patients in the UK about common side effects and bleeding patterns in an attempt to minimise patient dissatisfaction. In addition, patients with a high body mass index were excluded from the studies; therefore, these trials do not predict efficacy of Implanon in obese women.

Reviewed by Diana Mansour, MBChB, DFSRH, Consultant in Community Gynaecology, Contraception and Sexual Health Service, Newcastle upon Tyne Primary Care Trust, Newcastle upon Tyne, UK.

Safety and efficacy of a single-rod etonogestrel implant (Implanon): results from 11 international clinical trials.

Implanon® (etonogestrel implant) is currently the only contraceptive implant licensed in the UK and is familiar to most general practitioners and sexual and reproductive health care workers. This report, funded by Organon, provides an overview of the implant’s efficacy, safety and bleeding patterns. It is a summary of the findings of 11 clinical trials undertaken in contraceptive clinics in the USA, Chile, Asia and Europe.

In the 941 patients enrolled, no pregnancies occurred with the implant in situ, but there were six reported pregnancies within 14 days of implant removal. This gave a cumulative Pearl index of 0.38.

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Reviewed by Kate L. Darlow, MBChB, DFSRH, Specialist Registrar, St John’s Hospital, Livingston, West Lothian, UK.

Male hormonal contraception: a double-blind placebo-controlled study.

A hormonal contraceptive for men has been the subject of active research for over 50 years. During this time a large number of studies have been carried out that have clearly demonstrated a number of important points including, most crucially, that hormone-induced spermatogenic suppression can provide effective contraception for men, and that this is fully reversible. This can be achieved either with high doses of testosterone alone or, to reduce the dose, the testosterone is more usually given in combination with a progestogen, which is the case in this study.

Studies in this field have often been limited by small sample size and difficulties in comparing different treatments. It is therefore very encouraging to learn of this double-blind placebo-controlled design involving 354 men who received either a low- or high-release etonogestrel implant (the low-release implant being similar to Implanon® and with one-third of the weight of a standard testosterone implant). A total of 62 men were randomised in a 1:1 fashion to men taking Implanon® and men taking the Low-Etonogestrel Implanted Testosterone (LEIT) implant and with one-third of the weight of a standard testosterone implant. The implant was removed from 30 men in the LEIT group and 30 men in the Implanon group. The analysis.

Disappointingly, however, both Organon and Schering have announced that they do not intend to pursue this line of research. Optimism is only maintained by the ongoing efforts of bodies such as the World Health Organization and the National Institutes of Health who continue to be active in this field.

Reviewed by Richard A. Anderson, PhD, MBChB, Professor of Clinical Reproductive Science, Centre for Reproductive Biology, Queen’s Medical Research Institute, University of Edinburgh, Edinburgh, UK.