

**Contraception with Depogestin : A Local Manufactured  
Injectable Progestin**  
**การคุมกำเนิดด้วยยาฉีดคุมกำเนิดที่ผลิตในประเทศไทย Depogestin**

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ยาฉีดคุมกำเนิด Depot medroxyprogesterone acetate (DMPA) เป็นวิธีคุมกำเนิดชนิดหนึ่งที่ใช้ในโครงการวางแผนครอบครัวแห่งชาติ อย่างไรก็ตาม การศึกษาทางคลินิกถึงประสิทธิภาพและผลข้างเคียงของยาฉีดคุมกำเนิด DMPA ที่ผลิตภายในประเทศยังมีไม่มาก การศึกษานี้มีวัตถุประสงค์เพื่อศึกษาถึงประสิทธิภาพของยา ลักษณะระดู และผลข้างเคียงของยาฉีดคุมกำเนิด Depogestin ซึ่งเป็นยาฉีดคุมกำเนิดที่ผลิตในประเทศไทยโดยบริษัท ANB Laboratories จำกัด มีสตรีที่เข้าร่วมการศึกษา 100 ราย ติดตามการศึกษาเป็นระยะเวลา 1 ปี จากการศึกษาพบว่าอายุเฉลี่ยของผู้เข้าร่วมการศึกษาคือ  $23 \pm 5.6$  ปี มีบุตรเฉลี่ย  $1.2 \pm 0.6$  คน มีจำนวนเดือนที่ใช้ 828 เดือน มีอัตราการคงใช้เมื่อ 1 ปี ร้อยละ 30 ลักษณะระดูเมื่อใช้ครบ 1 ปี มีเลือดออกกะปริบกะปรอย ร้อยละ 36.7 ไม่มีระดู ร้อยละ 63.3 ผลข้างเคียงที่พบมากที่สุดคือระดูมากกะปริบกะปรอย ในระหว่างการศึกษานี้ สตรีที่ใช้ Depogestin ไม่มีการตั้งครรภ์ สรุปได้ว่ายาฉีดคุมกำเนิด DMPA ที่ผลิตภายในประเทศมีประสิทธิภาพและผลข้างเคียงไม่แตกต่างจากการศึกษาอื่นที่ผ่านมาของยาฉีดคุมกำเนิด DMPA ที่ผลิตจากต่างประเทศ

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**Abstract :** Surasak Taneepanichskul, Rosalin Kriengsinyot and Unnop Jaisamram. 2002. Contraception with Depogestin : a local manufactured injectable progestin. Thai J Hlth Resch 16(1) : 1-7.

Depot medroxyprogesterone acetate (DMPA) is only injectable contraceptive used in National Family Planning Program. However, only few clinical trials of local manufactured DMPA were studied. The objectives of the study were to evaluate efficacy, bleeding patterns and side effects of Depogestin, a local manufactured DMPA, use as contraceptive. One hundred women were participated in the study. The average age and parity were  $23 \pm 5.6$  years and  $1.2 \pm 0.6$  respectively. The total months use was 828 months and the continuation rate at 1 year was 30%. The rate of irregular bleeding and amenorrhea in one-year DMPA users were 36.7% and 63.3% respectively. Most common side effect was irregular bleeding. No pregnancy was occurred during Depogestin use. In summary, Depogestin, a local manufactured DMPA, was effective injectable contraceptive and had the same bleeding patterns and side effects as other studies.

**Key words :** contraception, injectable contraceptive

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## Introduction

The only injectable progestin which uses in National Family Planning Program (NFPP) is depot medroxyprogesterone acetate (DMPA) (Taneepanichskul, 2001). However, DMPA presently used in NFPP was either imported or local manufactured (Taneepanichskul, 2001).

Even the injectable progestins are approved by Food and Drug Administration Office, only few clinical trials of local manufactured DMPA were studied. Depogestin (ANB Laboratories Co., Ltd, Bangkok, Thailand), a local manufactured DMPA has been used in NFPP for many years. However, the clinical study of this product was not available. The objectives of this study were to evaluate efficacy, bleeding patterns and side effects of Depogestin use as contraceptive.

## Materials and methods

A cohort of Thai women, 20 – 40 years, using Depogestin as a contraceptive was studied between October 1, 1999 and September 30, 2001, at the Family Planning Unit, Department of Obstetrics and Gynaecology, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand.

One-hundred women were enrolled in this study. At the beginning, history taking, physical and pelvic examination were performed including Pap smear, blood pressure, and body weight measurements. Cases contraindicated against DMPA use were excluded. All subjects voluntarily used DMPA as a contraceptive and received 150 mg DMPA within 5 days after the onset of menstruation. Subsequent injections were scheduled at 12 week intervals. The bleeding patterns were recorded on a menstrual diary card. At each follow-up visit, the side effects were recorded on the follow-up forms, the menstrual diary cards were checked, and physical examination including body weight and blood pressure were routinely performed. If subject had irregular bleeding, management performed counseling. The SPSS/PC<sup>+</sup> (Chicago, IL, USA) for Windows<sup>®</sup> Statistical Package Program was used to analyze the data with a personal microcomputer. Statistical analysis was performed using mean, standard deviation, Student's t-test, and a 95 % confidence interval (CI). The level considered significant was below 0.05.

## Results

The characteristic profiles of the 100 women are summarized in Table 1. After 6 months, 72 subjects wished to continue use of DMPA (72%). Forty-six subjects used it for more than 9 months (46%). Beyond that, continuation rates declined. The one-year continuation rate was 30%. The total women-months of exposure among the 100 cases were 828 months.

**Table 1** Characteristics of DMPA users\*

Characteristics	N = 100	95 % CI
Age (year)	23 ± 5.6 (20 - 40)**	-
Parity	1.2 ± 0.6	-
Blood pressure		
Systolic (mm Hg)	108 ± 13.6	105, 111
Diastolic (mm Hg)	68 ± 7.3	66.6, 69.4
Body weight (kg)	49.5 ± 6.1	48.3, 50.7
Height (cm)	152.6 ± 4.8	152, 154

\*Value are presented as mean ± standard deviation

\*\*Presented in range

The reasons for discontinuation of DMPA are shown in Table 2. Irregular bleeding was the major reason for discontinuation (57.1%). Other side effects such as amenorrhea, change in weight, headache and dizziness were reported. With prolonged use, the rate of amenorrhea increased (Table 3). No pregnancy occurred during the study period.

**Table 2** Reason for discontinuation of DMPA

Reason for discontinuation	Number of cases	Percentage of all reasons
Menstrual disturbances	49	70.0
Irregular bleeding	40	57.1
Amenorrhea	9	12.9
Weight gain	8	11.4
Weight loss	2	2.9
Pregnancy desired	11	15.7
Total number of reasons	70	100.0

**Table 3** Proportion of cases with alteration of menstruation

Duration of use	Percentage of	
	Irregular bleeding	Amenorrhea
3 months	93.0 (93/100)	7.0 (7/100)
6 months	75.0 (54/72)	25.0 (18/72)
9 months	58.7 (27/46)	41.3 (19/46)
1 year	36.7 (11/30)	63.3 (19/30)

## Discussion

This study has demonstrated that Depogestin is highly effective injectable. Pregnancy could be prevented in all subjects who use it continuously. As shown in previous studies, the annual failure rate associated with DMPA use is 0.3%, comparable with the contraceptive efficacy of the other most reliable methods (tubal sterilization, subdermal implants and the Tcu 380 A) (Trussel and Kost, 1987; Chotnopparatpattara and Taneepanichskul, 2000).

In Thai women, DMPA was a popular contraceptive method. A national contraceptive prevalence survey in Thailand, conducted in 1996, reported that about DMPA was the second most contemporary contraceptive method (Taneepanichskul, 2001).

Continuous use of DMPA (48% in this study at 1 year) was less than other studies (Panle *et al.*, 1997; Davidson *et al.*, 1997). This may be due to poor compliance, or method switching. Short duration of child spacing may be another explanation (Chotnopparatpattara and Taneepanichskul, 2000).

The socioeconomic and educational status may be factors affecting the continuation rate (Panle *et al.*, 1997; Davidson *et al.*, 1997). Importantly, pretreatment counseling, as demonstrated by Lei *et al.* (1996) was a helpful method for improving the continuation rate. Kedar *et al.* (1998) have studied the efficacy of an intensive reminder system, receiving both mail and telephone remind compared with a scheduled appointment at the time of the previous injection. The study has concluded that the rate of continuation does not improve with an intensive reminder system.

As is well know, amenorrhea becomes more common with prolonged DMPA use. In this study, the rate of aminorrhea in one-year DMPA users was 63.3% that was higher than previously reported (Chotnopparatpattara and Taneepanichskul, 2000). Another finding in this study was that the number of days with irregular bleeding and spotting decreased over time. However, the management of irregular bleeding in DMPA users in our institute is only

counseling. We did not offer estrogen therapy or NSAIDS (non-steroidal anti-inflammatory drugs) for treating the bleeding problems while on DMPA because there is no all controlled study to prove the efficacy of long-term treatment in DMPA bleeders.

The main factor associate with discontinuation in this study was irregular bleeding which has also been demonstrated by other studies (Chotnopparatpattara and Taneepanichskul, 2000; Panle *et al.*, 1997). Weight gain was also a common side effect (Chotnopparatpattara and Taneepanichskul, 2000; Panle *et al.*, 1997). Chotnopparatpattara *et al.* (2000) found that weight gain was the most common side effects perceived. However, this study has shown that only 11.4% of the subjects discontinued DMPA due to weight gain. In long-term DMPA use, the change of body weight was not significantly different from that in long-term DMPA users (Taneepanichskul *et al.*, 1999). The gained weight is probably due to increased appetite rather than fluid retention (Taneepanichskul, 2001). Dietary control and regular exercise should be advised.

In conclusion, Depogestin is a highly effective contraceptive in Thai women. The longer a woman is on DMPA, the greater the likelihood, of amenorrhea. With time, the number of days the DMPA user has abnormal bleeding decrease. Weight gain as a side effect of DMPA use in these woman is unremarkable.

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