COMPARISON OF CHANGES OF MENSTRUAL CYCLE AS EFFECTS ON THE USE OF HORMONAL CONTRACEPTION IN COMBINATION OF INJECTION IN 1 MONTH, INJECTION IN 2 MONTHS, AND INJECTION IN 3 MONTHS

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Conflict of Interest statement

The authors declare that this research was conducted without any commercial of financial relationship that could be seen as a potential conflict of interest.

Ethics statements

Studies involving animal subjects

No animal studies are presented in this manuscript.

Studies involving human subjects

The studies involving human participants were reviewed and approved by Institutional review board of Universitas Sumatera Utara, Medan, Indonesia. Written informed consent for participation was required for this study.

Inclusion of identifiable human data

No potentially identifiable human images or data is presented in this study.

Data availability statement

The datasets generated for this study will not be made publicly available. The datasets for this manuscript are not publicly available because dissemination of data is not included in the study's IRB approval. Requests to access the datasets should be directed to Ryan Andrian, MD, at ryanandrian753@gmail.com

Abstract

Background: The contraception injection is the most widely used contraception including Cyclofem. In practice, synthetic progesterone may cause changes in the menstrual cycle and causes discomfort for the acceptor so the acceptor sometimes chooses to stop using it. This study was a follow-up study of clinical trial research phase III, from the group of acceptors using Gestin F2 and Gestin F3 injections compared to Cyclofem injections that have been done by previous researchers in which he conducted research to develop contraception injection Gestin F2® and Gestin F3®, with the aim to reduce discomfort and ineffective use of contraception injections.

Objective: To find out the difference in the cycle and menstrual duration in the use of hormonal contraceptive combination injections every 1 month (Cyclofem), contraception injections every 2 months and contraception injections every 3 months.

Methods: This research is a descriptive analytic study with Case Series design. To assess the difference between cyclofem, 2-month hormonal injections and 3-month hormonal injections in changes in the menstrual cycle. Multivariate statistical analysis was performed using the Kruskal Wallis test.

Results: This research was conducted on 120 people, divided by 3 gripus with of 40 people in each study group. The mean age in the 1-month injection study group was 30.9 years, the 2-month injection group 33.73 years and in the 3-month injection group with a mean age of 31.98 years. Evaluation of menstrual cycles in the 3 to 12 months appeared throughout the study group, the majority of menstrual cycles are normal with a mean cycle between 28-29 days. While the evaluation of menstrual length was done at the same time, it was found that the majority of menstrual periods were normal with an average of 5 days in all study groups. The p value obtained in the menstrual cycle with all three study groups was 0.387 ($p => 0.05$) and the p value for the duration of menstruation with all three study groups was 0.755 ($p => 0.05$).

Conclusion: There was no difference between the menstrual cycle and menstrual length in the three study groups.

Keywords: Menstrual cycle, injection hormonal contraception.

Background

The welfare of the Indonesian people can be improved by improving the quality of its individuals. One way to improve the quality of human resources is through a family planning program (KB). KB is expected to be a medium that helps the welfare of the community with convenient and easy methods, but in recent years there has been a stagnation in the use of family planning starting in the 2000s.[1,2]

The method of injection contraception is the most widely used method. This is because about 47.3% of women in Indonesia choose to use contraceptive methods that are not long-term. Cyclofem is an option for injectable contraceptive methods.[1]

The reason for choosing the method of injection contraception is inseparable from its practicality which does not require daily use and reduces the risk of "forgetting". Injectable contraception has a high effectiveness if used regularly according to a predetermined schedule. The accuracy of the injection is the key to the effectiveness of this method.[3]

The contraception injection is the most widely used contraception including Cyclofem. In practice, synthetic progesterone may cause changes in the menstrual cycle and causes discomfort for the acceptor so the acceptor sometimes chooses to stop using it. This study was a follow-up study of clinical trial research phase III, from the group of acceptors using Gestin F2 and Gestin F3 injections compared to Cyclofem injections that have been done by previous researchers in which he conducted research to develop contraception injection Gestin F2® and Gestin F3®, with the aim to reduce discomfort and ineffective use of contraception injections.

Methods

This research is a descriptive analytic study with Case Series design. To assess the difference between cyclofem, 2-month hormonal injections and 3-month hormonal injections in changes in the menstrual cycle. Multivariate statistical analysis was performed using the Kruskal Wallis test.

The study population was all medical record data in women using hormonal injection contraception combined with 1 month injection, injection every 2 months and injection per 3 months at the Helvetia Health Center. The sample in this study was part of the study population that met the inclusion and exclusion criteria which were secondary data taken from medical records. The sampling technique is by means of non probability sampling that is total sampling.

Results

This research was conducted on 120 people, divided by 3 gripus with of 40 people in each study group.

Table 1 presents the demographic characteristics of the study subjects. The mean age in the 1st month injection study group was 30.9 years, the injection group 2nd months was 33.73 years and in the group 3 injections was 3rd months with an average age of 31.98 years. Most education in the three groups is high school. Most subjects in the three groups work as private employees. The number of children in the three groups is 2 people.

Table 2 presents the vital signs of all subjects based on the mean value it appears that the vital signs of the subjects in the three groups in the border are normal. There were no differences in mean blood pressure, pulse frequency and height of the subjects using the Kruskal Wallis test.

Table 3 shows during 1 year of observation, it appeared that the subject's body weight was in the range of 60.15 to 61.43 kg. By using the Kruskal Wallis test it appears that there were no differences in body weight based on the type of injection for all observations (p> 0.05).

Table 4 presents in the 3rd month to 12th month, it appears that for the majority group (above 92.5%) the menstrual cycle is normal. At 3rd month, in the group with 1 injection, only 1 subject (2.5%) had a menstrual cycle in the polimenorea. Meanwhile, oligomenorrhoea were 2 subjects (5%) for the entire study group. The results of the analysis using the Kruskal Wallis test showed that there were no significant differences in proportions for menstrual cycle variables based on the type of injection (p = 0.837).

In the 6th month, in the group with 1 month injection, only 1 subject (2.5%) had a menstrual cycle in the polimenorea. Meanwhile, oligomenorrhea was 1 subject (2.5%) each for the 2nd month injection study group. The results of the analysis using the Kruskal Wallis test showed that there were no significant differences in proportions for menstrual cycle variables based on the type of injection (p = 0.267).

In the 9th month, in the group with 3-month injections, only 1 subject (2.5%) had a menstrual cycle. Meanwhile, oligomenorrhea as much as 1 person each (2.5%) for the 1 month injection study group, 2 subjects (5%) for the 2 month injection group and 1 person (2.5%) for the 3 month injection group . The results of the analysis using the Kruskal Wallis test showed that there were no significant differences in proportions for menstrual cycle variables based on the type of injection (p = 0.551).

At the 12th month, in the group with 1 month injection, only 1 subject (2.5%) had a menstrual cycle with polimenore. Meanwhile, oligomenorrhea as much as 1 subject each (2.5%) for the 1 month injection study group, 3 subjects (7.5%) for the 2 month injection group and 2 people (5%) for the 3rd month injection group . The results of the analysis using the Kruskal Wallis test showed that there were no significant differences in proportions for menstrual cycle variables based on the type of injection (p = 0.551).

Table 5 presents at 3rd month, in the group with 1 and 2 months injections, only 1 subject (2.5%) had hypomenorrhoea. Meanwhile, as much hypermenorrhea is one subject (2.5%) for the 1st month injection group. The results of the analysis using the Kruskal Wallis test showed that no significant difference in proportions was found for the menstrual length variable based on the type of injection (p = 0.837).

At 6th month, in the group with 3rd-month injections, there was 1 subject (2.5%) with hypomenorrhoea. There were no subjects with hypermenorrhea for the entire study group. The results of the analysis using the Kruskal Wallis test showed that no significant difference was found for the variable duration of menstruation based on the type of injection (p = 0.368).

At 9th month, in the group with 3-month injections, there was 1 subject (2.5%) with hypomenorrhoea. Meanwhile, hypermenorrhea as much as 1 subject each (2.5%) for the injection study group 2 and 3 months. The results of the analysis using the Kruskal Wallis test showed that no significant difference in proportions was found for the menstrual length variable based on the type of injection (p = 0.719).

At the 12th month, in the group with 2nd and 3rd months injections, there were 1 subject (2.5%) and 2 subjects (5%) with hypermenorrhea, respectively. Meanwhile, hypermenorrhea was 1 subject each (2.5%) for the 1 month injection study group and 4 subjects (10%) for the 2 month injection group. The results of the analysis using the Kruskal Wallis test showed that no significant difference was found for the variable duration of menstruation based on the type of injection (p = 0.093).

Table 6 presents in the 3rd and 6th month the whole group showed that a lot of menstrual blood in total ≤ 4 pad. At month 9, in the injection group 2 and 3 months there was one subject (2.5%) with a lot of menstrual blood> 4 pad. At 12 months there was 1 subject (2.5%) with menstrual blood types> 4 pad in group 1 injection and 2 subjects (5%) in group 2 injection. With using the Kruskal Wallis test showed no significant difference in proportions of many menstruation based on the type of injection (p> 0.05) for all observations (months 3 to 12).

Table 4.7, it is found that the average menstrual cycle in the three study groups is between 28-29 days with the p value obtained is 0.387 (p> 0.05) which means that there are no differences in menstrual cycles in the three study groups. Likewise, the menstrual period in which the three groups showed the same mean of 5 days with a p value obtained was 0.755 (p> 0.05) which also meant that there were no differences in menstrual length in the three study groups.

Conclusion

In conclusion, the average age of injection in the 1st month study group was 30.9 years, the injection group 2nd months was 33.73 years and in group 3 injections 3rd months with an average age of 31.98 years. In 3rd to 12th months, it appears that for the entire study group, the majority of the menstrual cycle was normal. The analysis found no significant difference in proportions for menstrual cycle variables based on the type of injection. For the entire study group, the majority of menstrual periods were normal. From the results of the analysis found no significant difference in proportion to the variable duration of menstruation based on the type of injection. The average menstrual cycle in the three study groups was between 28-29 days and menstrual periods in which all three groups showed the same mean of 5 days, where there was no difference between the menstrual cycle and menstrual length in the use of the three study groups.

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Table 1. Charateristics of research subjects

Charateristics	Group		
	injection 1 month, n=40	injection 2 months, n=40	Injection 3 months, n=40
Age, mean (SD), year	30,9 (8,89)	33, 73 (4,04)	31,98 (3,93)
education, n (%)			
Not school	0	3 (7,5)	1 (2,5)
Junior high school	7 (17,5)	10 (25)	8 (20)
Senior high school	30 (75)	23 (57,5)	26 (65)
Collage	3 (7,5)	4 (10)	5 (12,5)
Job, n (%)			
Trader	4 (10)	0	1 (2,5)
Freelancer	0	0	1 (2,5)
Farmer	1 (2,5)	2 (5)	2 (5)
Government employee	2 (5)	1 (2,5)	4 (10)
Entrepreuner	17 (42,5)	21 (52,5)	17 (42,5)
Tidak bekerja	16 (40)	16 (40)	15 (37,5)
Banyak Anak, n (%)			
1	12 (30)	9 (22,5)	10 (25)
2	14 (35)	19 (47,5)	23 (57,5)
3	11 (27,5)	5 (12,5)	6 (15)
4	3 (7,5)	3 (7,5)	1 (2,5)
5	0	4 (10)	0

Table 2. Vital sign examination results

Vital sign	Group			p
	Injection1 month, n=40	Injectio 2 months, n=40	injection3 months, n=40	
Systolic pressure, mean(SD), mmHg	115,63 (7,27)	118 (11,97)	117,63 (9,54)	0,397
Dyastolic pressure, mean(SD), mmHg	73,5 (4,83)	74,63 (5,93)	72,38 (5,19)	0,158
Heart frequency, mean(SD), x/m	80 (2,60)	80,03 (3,74)	80,43 (3,76)	0,781
Height ody, mean(SD), cm	157,38 (5,23)	156,25 (5)	157,15 (6,35)	0,499

Tabel 3. Body weight examination result

Body weight	Group			P
	Injection 1 month, n=40	Injection 2 month, n=40	Injection 3 month, n=40	
3th month, mean(SD), kg	60,33 (7,90)	60,23 (7,87)	60,98 (11,98)	0,935
6th month, mean(SD), kg	60,45 (7,63)	60,15 (7,72)	60,70 (12,35)	0,980
9th month, mean (SD), kg	60,38 (7,56)	60,10 (7,40)	60,93 (12,20)	0,964
12th month, mean(SD), kg	60,38 (7,49)	60,13 (7,32)	61,43 (11,49)	0,929

Table 4.The difference menstrual cycle based type of injection

Smenstrual cycle	KGroup			P
	injection 1 month, n=40	Injection 2 months, n=40	injection 3 months, n=40	
3th month				
Polimenorea	1 (2,5)	0	0	0,873
Normal	37 (92,5)	38 (95)	38 (95)	
Oligomenorea	2 (5)	2 (5)	2 (5)	
6th month				
Polimenorea	1 (2,5)	0	0	0,267
Normal	39 (97,5)	39 (97,5)	39 (97,5)	
Oligomenorea	0	1 (2,5)	1 (2,5)	
9th month				
Polimenorea	0	0	1 (2,5)	0,551
Normal	39 (97,5)	38 (95)	38 (95)	
Oligomenorea	1 (2,5)	2 (5)	1 (2,5)	
12th month				
Polimenorea	1 (2,5)	0	0	0,366
Normal	38 (95)	37 (92,5)	38 (95)	
Oligomenorea	1 (2,5)	3 (7,5)	2 (5)	

Table 5. The difference of along menstrual based type of injection P

Length of menstrual	Group			P
	Injection 1 month, n=40	Injection 2 month, n=40	Injection 3 month, n=40	
3th month				
Hipomenorea	1 (2,5)	1 (2,5)	0	0,719
Normal	38 (95)	39 (97,5)	40 (100)	
Hipermenorea	1 (2,5)	0	0	
6th month				
Hipomenorea	0	0	1 (2,5)	0,368
Normal	40 (100)	40 (100)	39 (97,5)	
9th month				
Hipomenorea	0	0	1 (2,5)	0,719
Normal	40 (100)	39 (97,5)	38 (95)	
Hipermenorea	0	1 (2,5)	1 (2,5)	
12th month				
Hipomenorea	0	1 (2,5)	2 (5)	0,093
Normal	39 (97,5)	35 (87,5)	38 (95)	
Hipermenorea	1 (2,5)	4 (10)	0	

Table 6. The difference of volume menstrual based type of injection

Volume menstrual	Group			p
	Injection 1 month, n=40	Injection 1 month, n=40	Injection 1 monthn, n=40	
Bulan 3th month				
40 (100)	40 (100)	40 (100)	40 (100)	1,000
6th month				
≤ 4 pad	40 (100)	40 (100)	40 (100)	1,000
9th month				
≤ 4 pad	40 (100)	39 (97,5)	39 (97,5)	0,604
>4 pad	0	1 (2,5)	1 (2,5)	
12th month				
≤ 4 pad	39 (97,5)	38 (95)	40 (100)	0,362
>4 pad	1 (2,5)	2 (5)	0	

Table 7. The difference and mean of cycle menstrual and length of menstrual while used injection 1 month, inection combination 2 months and inection combination 3 months

Variable	Cycle of menstrual			Length of menstrual		
	Mean	Median	SD	Mean	Median	SD
Injection 1 month	28	28	3	5	5	1
Injection combination 2 months	29	29	3	5	5	1
Injection combination 3 months Bulan	28	28	3	5	5	1
P Value*	0, 387			0,755		