



	Clinical Study III
Test Method	Multi Center, Randomized double-blind placebo-controlled study
Study Location	Aju University Medical Center Anam Hospital of Korea Univ. Severance Hospital of Yonsei Univ.
Test period	12 weeks
Dosage	638 mg tablet orally twice a day
Study Participants	96 female participants of age of 40~70 with menopausal symptoms
Inclusion Criteria	Age of 40 ~ 70 with menopausal symptoms





- **Significantly Improved!**

- Hot flash
- Paresthesia
- Nervousness
- Fatigue
- Melancholia
- Vertigo
- Formication
- Rheumatic pain
- Vaginal Dryness

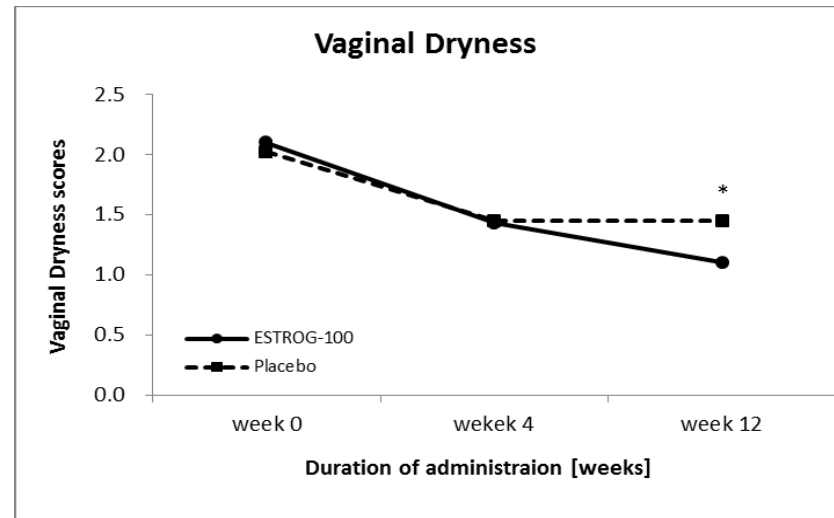
- The result almost **duplicate the 2nd Clinical Study (Non-Asian)** by **improving as many as 10 different symptoms** when we add insomnia since the improvement of trouble sleeping is marginally significant ($p=0.052$) in terms of efficacy.
- No significant differences or changes observed when measured endometrial thickness.
- No change in weight, BMI, and the level of estrogen and FSH without any adverse event reported during the study. The **endometrial thickness was measured to be observed not to change** in addition.





		Placebo	ESTROG-100	
		N=47	N=49	
		Mean±SD	Mean±SD	
Week0 (Baseline)		2.02±0.90	2.10±0.82	
Week 4		1.45±1.10	1.43±1.10	
Change	from	-0.57±1.14	-0.67±0.94	>0.05
baseline				
	p-value**	<0.01	<0.01	
Week 12		1.45±1.06	1.10±1.12	
Change	from	-0.57±1.16	-1.00±0.98	<0.05
baseline				
	p-value**	<0.01	<0.01	







	Placebo	ESTROG-100	
	N=47	N=49	
	Mean±SD	Mean±SD	
Week0 (Baseline)	33.06±7.76	35.14±8.11	
Week4	24.72±9.38	23.20±9.25	
Change from baseline	-8.34±8.56	-11.94±10.41	<0.05
p-value**	<0.01	<0.01	
Week12	20.11±10.33	14.84±9.94	
Change from baseline	-12.96±13.09	-20.31±12.07	<0.01
p-value**	<0.01	<0.01	



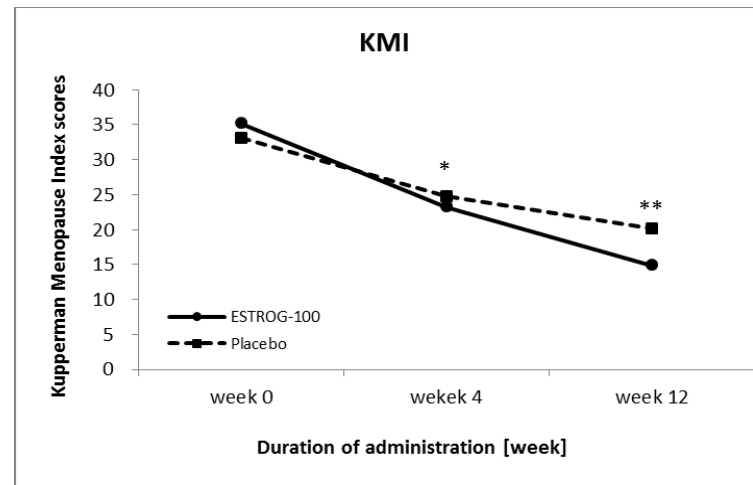


Fig. 1. Changes of Kupperman Menopause Index (Mean±SE) during 12 weeks administration of EstroG-100 and placebo.
SE: Standard Error, *: Statistically significant compared between groups; $p < 0.05$
**: Statistically significant compared between groups; $p < 0.01$ by t-test(ITT)



	EstroG-100 (N=49)					Placebo (N=47)				
	Week 0 (Baseline)	Week 4	Change from baseline	Week 12	Change from baseline	Week 0 (Baseline)	Week 4	Change from baseline	Week 12	Change from baseline
Hot Flush	2.10±0.92	1.53±0.96 ^{†***}	-0.57±1.00	0.84±0.92 ^{†**}	-1.27±1.09	2.09±0.86	1.68±0.89 [†]	-0.40±0.85	1.26±0.85 [†]	-0.83±1.13
Paresthesia	2.08±0.81	1.29±0.84 ^{†**}	-0.80±0.87	0.94±0.85 ^{†**}	-1.14±1.04	1.87±0.88	1.47±0.91 [†]	-0.40±0.90	1.26±0.92 [†]	-0.62±1.19
Insomnia	2.43±0.79	1.51±1.00 ^{†***}	-0.92±1.08	1.06±0.99 ^{†#}	-1.37±1.13	2.23±0.76	1.47±1.10 [†]	-0.77±1.07	1.26±1.07 [†]	-0.98±1.19
Nervousness	2.31±0.68	1.53±0.84 ^{†***}	-0.78±0.87	0.92±0.79 ^{†**}	-1.39±1.00	2.13±0.80	1.57±0.93 [†]	-0.55±0.77	1.17±0.84 [†]	-0.96±1.00
Melancholia	2.10±0.80	1.41±0.70 ^{†***}	-0.69±0.94	0.90±0.77 ^{†**}	-1.20±1.02	1.89±0.81	1.32±0.86 [†]	-0.57±0.80	1.15±0.69 [†]	-0.74±1.01
Vertigo	1.63±0.88	1.14±0.89 ^{†***}	-0.49±0.94	0.67±0.80 ^{†**}	-0.96±0.89	1.55±0.95	1.06±0.76 [†]	-0.49±1.08	1.09±0.86 [†]	-0.47±1.23
Fatigue	2.47±0.65	1.78±0.92 ^{†**}	-0.69±0.87	1.27±0.93 ^{†*}	-1.20±1.02	2.11±0.81	1.72±0.90 [†]	-0.38±0.77	1.47±0.88 [†]	-0.64±1.09
Rheumatic pain	2.18±0.70	1.41±0.93 ^{†**}	-0.78±0.96	0.96±0.96 ^{†**}	-1.22±0.98	2.19±0.88	1.77±0.96 [†]	-0.43±0.83	1.43±0.88 [†]	-0.77±1.07
Headaches	1.65±1.03	0.98±0.85 ^{†***}	-0.67±0.99	0.73±0.78 ^{†***}	-0.92±1.10	1.64±0.92	1.13±0.99 [†]	-0.51±0.98	0.94±0.92 [†]	-0.70±1.04
Palpitation	1.80±0.89	1.08±0.81 ^{†***}	-0.71±0.96	0.65±0.72 ^{†***}	-1.14±1.02	1.79±0.91	1.19±0.95 [†]	-0.60±1.06	0.94±0.79 [†]	-0.85±1.16
Formication	1.27±1.06	0.63±0.81 ^{†**}	-0.63±1.09	0.47±0.77 ^{†**}	-0.80±1.06	1.09±0.93	0.79±0.86 [†]	-0.30±1.06	0.72±0.83 [†]	-0.36±0.97

