

NCT : 1690/KEPK/XII/2019

Title : The Effect of Combination Therapy Using Li-ESWT and PDE-5 Inhibitor
Compared to PDE-5 Inhibitor Alone in Patients With Erectile Dysfunction

Date : June 14, 2020

Characteristics of Trial Subjects

ID	GROUP	INITIAL	EHS PRE	IIEFS PRE	ED SEVERITY (Years)	ED DURATION N (Years)	AGE	AGE OF SPOUSE	MARRIAGE DURATION (Years)	WAIST CIRCUMFERENCE (cm)	BMI (kg/m ²)	KOMORBID
1	1	ELB	2	17	mild	5.00	40	37	12	84	25.1	Dislipidemia, Stroke
2	1	RUD	2	17	mild	1.50	54	50	27	89	22.0	HT, Smoking
3	2	ANZ	3	17	mild	1.00	47	48	17	111	33.5	DM, HT
4	1	BIL	2	17	mild	0.25	54	54	29	92	27.1	DM, HT, Dislipidemia
5	1	YUD	2	14	mild-moderate	0.25	43	40	7	89	23.3	
6	2	EDI	3	20	mild	9.00	45	41	23	90	26.4	Gastritis
7	2	EDH	2	16	mild-moderate	1.50	48	46	19	91	23.3	DM
8	2	SAM	2	15	mild-moderate	0.67	44	42	24	92	23.3	HNP, Vertigo
9	2	AGW	2	19	mild	2.00	53	52	32	102	31.2	HT-Dislipidemia, Urinary Stone, LOH, Alcoholism, Smoking
11	2	ALI	2	16	mild-moderate	0.67	48	38	25	97	27.2	DM, HT, Dislipidemia, LOH, Smoking
12	2	SAP	3	12	mild-moderate	0.33	52	52	32	113	32.2	DM, HT, Heart Disease, CKD on HD, Hiperuricemia, LOH, Smoking, Dislipidemia
13	1	TRI	2	16	mild	1.50	49	40	24	102	29.0	DM, Stroke, Merokok
14	2	SAT	2	10	moderate	6.50	49	45	21	102	31.5	Dislipidemia, LOH
16	1	MAM	1	9	moderate	2.00	44	36	14	75	22.2	Hernia
17	1	GOD	2	19	mild	0.50	54	48	22	102	30.5	Stroke, Dislipidemia, Smoking
20	1	HOT	3	18	mild	5.00	47	48	18	112	32.5	HT, STD
21	1	KHO	1	10	moderate	0.67	50	51	29	99	27.9	DM, Hiperuricemia
22	1	ROC	3	21	mild	0.50	43	46	19	92	24.6	Heart disease, Smoking
23	2	MAD	1	10	moderate	0.50	46	30	11	75	18.2	Hernia
24	2	FIR	1	10	moderate	5.00	51	50	27	101	26.5	DM, HT, Heart disease, Meningitis
25	1	EDD	2	10	moderate	1.00	43	37	20	73.5	18.2	TB, Hepatitis, HT, Heart disease, Smoking, Alcoholism
26	2	EKO	2	11	moderate	10.00	53	50	25	99	23.5	DM, HT, Heart disease, HNP, BPH
27	2	BNA	3	20	mild	2.00	47	45	19	95	29.0	Dislipidemia, LOH
28	2	EDO	2	17	mild	2.00	55	53	26	100	29.3	
29	1	RAT	2	16	mild-moderate	2.00	53	49	30	87	26.1	
30	2	PAR	2	12	mild-moderate	6.00	51	51	35	103	30.1	HT, Dislipidemia, Smoking

Notes :

Kelompok 1 = control group (single therapy)

Kelompok 2 = test group (combination therapy)

Result Table

ID	INITIAL	GROUP	Pretest PSV	Posttest PSV	Delta Pre-Post PSV	Pretest VEGF	Posttest VEGF	Delta Pre-Post VEGF	Pretest IIEF5	Posttest IIEF5	Delta IIEF5	Pretest EHS	Posttest EHS	Delta EHS
1	ELB	1	10.20	11.10	0.90	97.67	100.11	2.44	17	20	3	2	3	1
2	RUD	1	14.00	14.20	0.20	152.61	137.96	-14.65	17	21	4	2	3	1
3	ANZ	2	10.70	13.00	2.30	64.47	81.39	16.92	17	22	5	3	4	1
4	BIL	1	14.20	20.80	6.60	83.02	61.72	-21.30	17	19	2	2	3	1
5	YUD	1	9.60	11.35	1.75	56.92	53.49	-3.43	14	17	3	2	3	1
6	EDI	2	11.00	14.00	3.00	96.05	139.18	43.13	20	25	5	3	4	1
7	EDH	2	11.65	16.15	4.50	23.96	24.32	0.36	16	25	9	2	4	2
8	SAM	2	9.25	9.00	-0.25	43.21	80.17	36.96	15	22	7	2	4	2
9	AGW	2	12.90	14.95	2.05	86.28	100.33	14.05	19	25	6	2	4	2
11	ALI	2	14.10	17.95	3.85	41.15	93.99	52.84	16	23	7	2	3	1
12	SAP	2	10.80	13.95	3.15	30.18	67.56	37.38	13	25	12	2	4	2
13	TRI	1	8.50	8.85	0.35	55.55	77.33	21.78	16	21	5	2	3	1
14	SAT	2	8.20	11.75	3.55	40.46	70.64	30.18	10	25	15	2	4	2
16	MAM	1	7.95	8.70	0.75	71.99	79.77	7.78	9	9	0	1	1	0
17	GOD	1	15.50	15.30	-0.20	37.72	45.95	8.23	19	23	4	2	4	2
20	HOT	1	15.50	16.50	1.00	23.96	14.08	-9.88	18	25	7	3	4	1
21	KHO	1	5.20	7.85	2.65	71.95	82.21	10.26	10	21	11	1	3	2
22	ROC	1	14.65	14.50	-0.15	87.07	70.64	-16.43	21	22	1	3	3	0
23	MAD	2	7.90	12.70	4.80	21.03	26.75	5.72	10	24	14	1	3	2
24	FIR	2	10.70	12.40	1.70	91.98	102.15	10.17	10	14	4	1	3	2
25	EDD	1	8.55	8.95	0.40	106.63	173.77	67.14	10	19	9	2	3	1
26	EKO	2	11.10	13.00	1.90	67.21	159.94	92.73	11	19	8	2	3	1
27	BNA	2	12.45	14.90	2.45	98.89	134.71	35.82	20	23	3	3	4	1
28	EDO	2	13.00	14.25	1.25	58.98	69.95	10.97	17	21	4	2	4	2
29	RAT	1	12.90	14.05	1.15	14.45	52.12	37.67	16	25	9	2	4	2
30	PAR	2	12.25	14.40	2.15	61.04	69.27	8.23	12	25	13	2	4	2

Notes :

Group 1 : control group (single therapy)

Group 2 : test group (combination therapy)

Table 1. Subjects characteristics

Characteristics		Control Group n=12	Experimental Group n=14	Total n=26	p
Mean Age		47.8 yo	49.2 yo	48.6 yo	0,419
Mean Spouses' age		44.7 yo	45.9 yo	45.3 yo	0,620
Mean Duration of ED (years)		1.7 years	3.4 years	2.6 years	0.147
Mean of waist circumference (cm)		91.4	97.9	94.9	0.118
Mean BMI (kg/m ²)		25.7	27.5	26.7	0.277
Comorbidities	Diabetes Mellitus	25%	42.9%	34.6%	
	Hypertension	33.3%	42.9%	38.5%	
	Cardiac problems	16.7%	21.4%	19.2%	
	Dyslipidemia	25%	50%	38.5%	
	Hypogonadism	0%	35.7%	19.2%	
	History of smoking	41.7%	28.6%	34.6%	
	History of alcoholism	8.3%	7.1%	7.7%	
	Other	50%	57.1%	53.8%	
ED Severities	Mild	58.3%	35.7%	46.2%	
	Mild-Moderate	16,7%	35.7%	26.9%	
	Moderate	25%	28.6%	26.9%	
Median of EHS	2 (1-3)	2 (1-3)	2 (1-3)	0.573	
Median of IIEF-5	16.5 (9-21)	15.5 (10-20)	16 (9-21)	0.716	

Note : n = number of samples, ED = erectile dysfunction, BMI = body mass index, EHS = erection hardness score, IIEF = International index of errectal function
Comparison of IIEF-5, EHS, and mean duration of ED were done using Mann-Whitney test, as for other parameters, Independent T-test were used.

Table 2. Comparison of IIEF-5 scores

Subject	IIEF-5 Score			Pre-test – Post-test Comparison p
	Pre-test	Post-test	Delta	
Control Group (n=12)	16.5 (9-21)	21 (9-25)	4 (0-12)	0.004*
Experimental Group (n=14)	15.5 (10-20)	23.5 (14-25)	7 (3-15)	0.001*
Total (n=26)	16 (9-21)	22 (9-25)	5.5 (0-15)	

Note : IIEF=International index of erectile function, n=number of sample, * = sign of significance ($p < 0.05$)

Comparison of pre- and post-test IIEF-5 parameter was done using Wilcoxon's test

Table 3. Comparison of EHS scores

Subject	EHS core			Pre-test – Post-test Comparison p
	Pre-test	Post-test	Delta	
Control Group (n=12)	2 (1-3)	3 (1-4)	1 (0-2)	0.004*
Experimental Group (n=14)	2 (1-3)	4 (3-4)	2 (1-2)	0.001*
Total (n=26)	2 (1-3)	3.5 (1-4)	1 (0-2)	

Note : EHS = Erection hardness score, n = number of sample, * = sign of significance ($p < 0.05$)

Comparison of pre- and post-test EHS parameter was done using Wilcoxon's test

Table 4. Comparison of VEGF values

Subject	VEGF Level (pg/ml)			Pre-test – Post-test Comparison p
	Pre-test	Post-test	Delta	
Control Group (n=12)	59.92	66.24	6.32	0.408
	±	±	±	
Experimental Group (n=14)	41.91	49.42	25.43	0.001*
	57.95	84.65	26.69	
Total (n=26)	±	±	±	
	25.92	40.71	24.23	
	58.86	76.15	17.29	
	±	±	±	
	33.52	44.99	26.40	

Note : VEGF = Vascular Endothelial Growth Factor, n = number of sample, * = sign of significance ($p < 0.05$)

Comparison of pre- and post-test VEGF parameter was done using Paired T-test.

Table 5. Comparison of PSV values

Subject	PSV (cm/s)			Pre-test – Post-test Comparison p
	Pre-test	Post-test	Delta	
Control Group (n=12)	11.40	12.68	1.28	0.04*
	±	±	±	
	3.47	3.90	1.86	
Experimental Group (n=14)	11.14	13.74	2.60	0.001*
	±	±	±	
	1.79	2.10	1.34	
Total (n=26)	11.26	13.25	1.99	
	±	±	±	
	2.64	3.04	1.70	

Note : PSV = Peak Systolic Velocity, n = number of sample, * = sign of significance (p < 0.05)

Comparison of pre- and post-test PSV parameter was done using Paired T-test.

Table 6. Comparison of all parameters between groups

Parameter		Control Group	Experimental Group	p
IIEF-5	Pre-test	16.5 (9-21)	15.5 (10-20)	0.716
	Post-test	21 (9-25)	23.5 (14-25)	0.047*
	Delta	4 (0-11)	7 (3-15)	0.047*
EHS	Pre-test	2 (1-3)	2 (1-3)	0.573
	Post-test	3 (1-4)	4 (3-4)	0.018*
	Delta	1 (0-2)	2(1-2)	0.032*
VEGF	Pre-test	59.92 ± 41.91	57.95 ± 25.92	0.885
	Post-test	66.24 ± 49.42	84.65 ± 40.71	0.308
	Delta	6.32 ± 25.43	26.69 ± 24.23	0.023*
PSV	Pre-test	11.40 ± 3.47	11.14 ± 1.79	0.813
	Post-test	12.68 ± 3.90	13.74 ± 2.10	0.385
	Delta	1.28 ± 1.86	2.60 ± 1.34	0.009*

Note : IIEF = International index of erectile function, EHS = Erection hardness score, PSV = Peak Systolic Velocity, VEGF = Vascular Endothelial Growth Factor, * = statistically significant (p < 0.05)

Comparison between groups for pre-test and post-test VEGF parameters were done using Independent T-test, as for the others parameters, the statistics methods used was Mann-Whitney test