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Lampiran 1. Persetujuan Etik





REKOMENDASI PERSETUJUAN ETIK

Nomor : 47/UN4.6.4.5.31/ PP36/ 2022

Tanggal: 31 Januari 2022

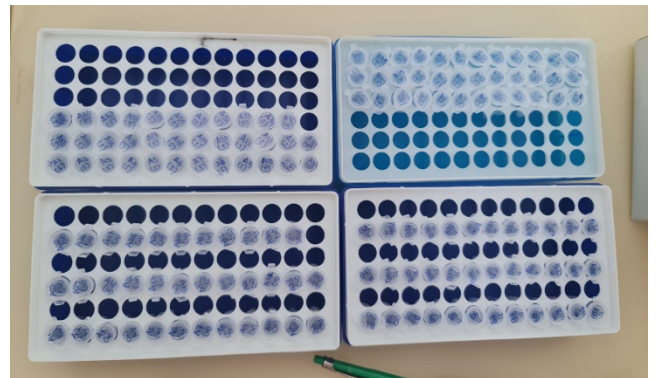
Dengan ini Menyatakan bahwa Protokol dan Dokumen yang Berhubungan Dengan Protokol berikut ini telah mendapatkan Persetujuan Etik :

No Protokol	UH22010004	No Sponsor	
Peneliti Utama	Prof. Dr. dr. Anis Irawan Anwar, Sp.KK(K), FINSDV, FAADV	Sponsor	
Judul Peneliti	EFEKTIVITAS MIKROBIOM TOPIKAL YANG MENGANDUNG LACTOBACILLUS PLANTARUM TERHADAP KADAR IL 8, IL 12, TNF ALPHA DAN ANTI INFLAMASI IL 10 SEBAGAI PENGOBATAN ACNE VULGARIS		
No Versi Protokol	2	Tanggal Versi	28 Januari 2022
No Versi PSP	2	Tanggal Versi	28 Januari 2022
Tempat Penelitian	RS Universitas Hasanuddin dan RS Dr. Wahidin Sudirohusodo Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input checked="" type="checkbox"/> Fullboard Tanggal 18 Januari 2022	Masa Berlaku	Frekuensi review lanjutan
Ketua KEPK FKUH RSUH dan RSWs	Nama Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K)	Tanda tangan	
Sekretaris KEPK FKUH RSUH dan RSWs	Nama dr. Agussalim Bulhari, M.Med.,Ph.D.,Sp.GK (K)	Tanda tangan	

Kewajiban Peneliti Utama:

- Menyerahkan Amendemen Protokol untuk persetujuan sebelum di implementasikan
- Menyerahkan Laporan SAE ke Komisi Etik dalam 24 jam dan dilengkapi dalam 7 hari dan Laporan SUSAR dalam 72 Jam setelah Peneliti Utama menerima laporan
- Menyerahkan Laporan Kemajuan (progress report) setiap 6 bulan untuk penelitian resiko tinggi dan setiap setahun untuk penelitian resiko rendah
- Menyerahkan laporan akhir setelah Penelitian berakhir
- Melaporkan penyimpangan dari protokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan

Lampiran 2. Alat dan Bahan



Lampiran 3. Inform Consent

**SURAT PERNYATAAN PERSETUJUAN
UNTUK IKUT SERTA DALAM PENELITIAN
(*INFORMED CONSENT*)**

Yang bertanda tangan dibawah ini:

N a m a :

U s i a :

Alamat :

Pekerjaan :

No. KTP/lainnya:

Dengan ini menyatakan bahwa:

Telah memperoleh penjelasan sepenuhnya, menyadari, mengerti, dan memahami tentang tujuan, manfaat dan risiko yang mungkin timbul dalam penelitian yang berjudul:

“Efektivitas Mikrobiom Topikal yang Mengandung Lactococcus Ferment Lysate Terhadap IL 12, IL 8, TNF Alpha, IL 10, dan IL 1 sebagai Pengobatan Akne Vulgaris”

Maka dengan ini saya menyatakan :

setuju/tidak setuju*) berperan serta dalam penelitian ini

Demikian surat pernyataan ini kami buat dengan sesungguhnya dan tanpa paksaan.

Makassar, 2022

Peserta penelitian,

(.....)



KUISISIONER PENELITIAN

Efektivitas Mikrobiom Topikal yang Mengandung Lactococcus Ferment Lysate Terhadap IL 12, IL 8, TNF Alpha, IL 10 dan IL 1 sebagai Pengobatan Akne Vulgaris

Nama : Berat Badan : Kg

Umur : Tahun Tinggi : Cm

Alamat:

No. Telpon :

ID LINE:

Pendidikan Terakhir :
1. SD
2. SMP
3. SMA/Sederajat
4. Akademi/Sarjana
5. Sekolah.....

Agama :
1. Islam
2. Kristen
3. Hindu
4. Budha
5. Lainnya.....

Pekerjaan :
1. Pelajar
2. Mahasiswa
3. PNS
4. Swasta
5. Lainnya.....

Aktivitas Rutin :
1. Luar Ruangan
2. Dalam Ruangan

Apakah mengalami stres dalam waktu : 1. Ya 2. Tidak

Kebiasaan memencet jerawat :

Merokok : 1. Ya 2. Tidak

Alkohol : 1. Ya 2. Tidak

Riwayat keluarga menderita jerawat: 1. Ayah 3. Kakak/Adik
2. Ibu 4. Lainnya.....

Kebiasaan Makan :

Kacang: 1. Setiap hari 2. Sekali Seminggu 3. Sekali sebulan 4. Tidak pernah

Coklat : 1. Setiap hari 2. Sekali Seminggu 3. Sekali sebulan 4. Tidak pernah

Makanan pedes: 1. Setiap hari 2. Sekali Seminggu 3. Sekali sebulan 4. Tidak pernah

Riwayat Jerawat : 1. <6bulan 2. > 6bulan

Pemakaian Kosmetik : 1. Ya 2. Tidak

Jika "Ya", Kosmetik yang digunakan:.....

Mencuci muka sehari : 1. Satu kali 3. Tiga kali 5. Tidak pernah
2. Dua kali 4. > Tiga kali

Riwayat penggunaan obat untuk jerawat: 1. Ya 2. Tidak

Jika " Ya ", obat yang digunakan.....

Apakah sudah menikah : 1. Ya 2. Tidak

Tidur Teratur : 1. Ya 2. Tidak

Apakah menstruasi Anda teratur tiap bulan? : 1. Ya 2. Tidak

Kapan Terakhir Haid :

Berapa lama menstruasi Anda? :
1. <5hari
2. 5-7 hari
3. > 7hari

Berapa lama panjang siklus menstruasi Anda? (siklus menstruasi adalah rata-rata jumlah hari dari rentang hari pertama menstruasi awal sampai hari pertama menstruasi berikutnya, selama 3 bulan terakhir):
1. <24 hari
2. 24 - 30 hari
3. >30 hari

**** Manifestasi Klinik**

Komedo :

Papul :

Pustul :

Daerah wajah	Hari 0	Hari 14	Hari 28

NB: **Diisi oleh peneliti

Makassar,

2022

()

Lampiran 5. Data Sampel

Perbandingan Penggunaan Krim A dan B Sebelum (W0) dan Sesudah (W8)

Case Processing Summary

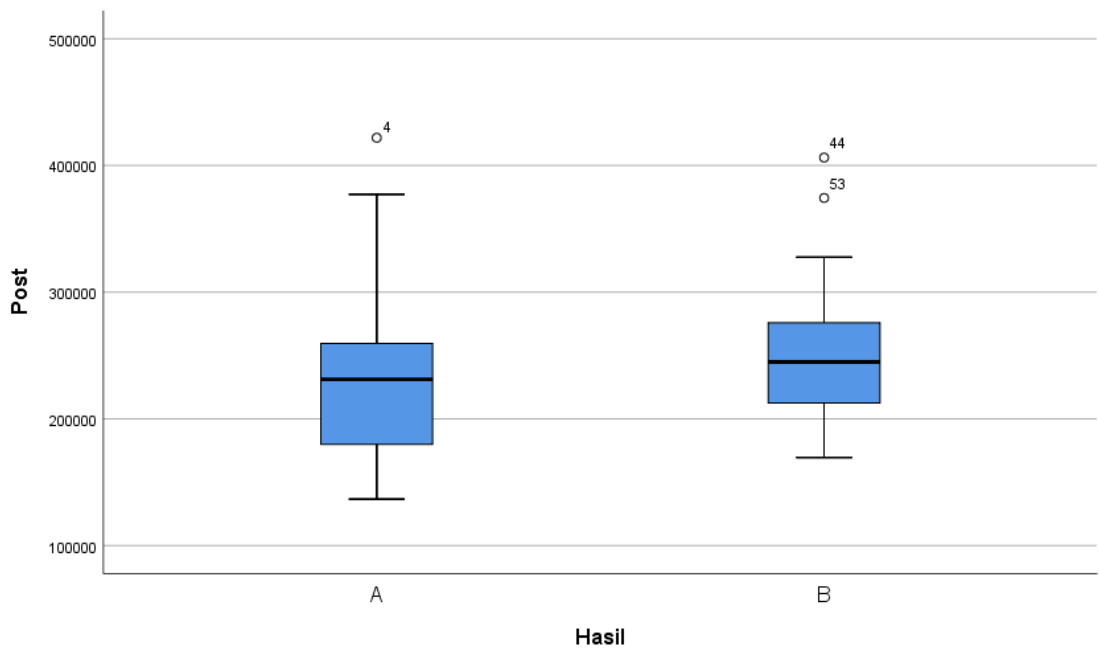
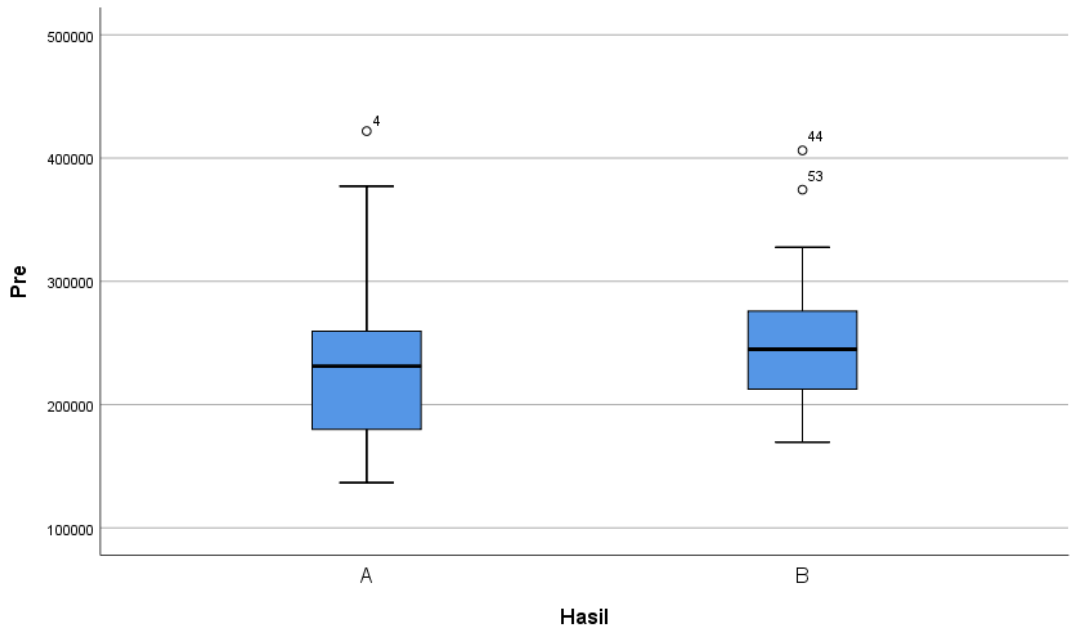
		Cases					
		Valid		Missing		Total	
	Hasil	N	Percent	N	Percent	N	Percent
Pre	A	35	100.0%	0	0.0%	35	100.0%
	B	35	100.0%	0	0.0%	35	100.0%
Post	A	35	100.0%	0	0.0%	35	100.0%
	B	35	100.0%	0	0.0%	35	100.0%

Descriptives

		Hasil	Statistic	Std. Error
Pre	A	Mean	253736.83	9778.303
		95% Confidence Interval for Mean	Lower Bound	233864.93
		Upper Bound	273608.73	
		5% Trimmed Mean	249607.16	
		Median	240603.00	
		Variance	3346532022.087	
		Std. Deviation	57849.218	
		Minimum	172603	

		Maximum	432909	
		Range	260306	
		Interquartile Range	69098	
		Skewness	1.039	.398
		Kurtosis	1.502	.778
	B	Mean	257184.09	9335.636
		95% Confidence Interval for Mean	Lower Bound	238211.79
			Upper Bound	276156.38
		5% Trimmed Mean	253656.30	
		Median	246848.00	
		Variance	3050393428.610	
		Std. Deviation	55230.367	
		Minimum	181367	
		Maximum	407459	
		Range	226092	
		Interquartile Range	65638	
		Skewness	.800	.398
		Kurtosis	.602	.778
Post	A	Mean	233706.17	10580.820
		95% Confidence Interval for Mean	Lower Bound	212203.36
			Upper Bound	255208.98
		5% Trimmed Mean	229655.36	
		Median	231192.00	
		Variance	3918381076.323	

		Std. Deviation	62596.973	
		Minimum	136725	
		Maximum	421872	
		Range	285147	
		Interquartile Range	81043	
		Skewness	.943	.398
		Kurtosis	1.509	.778
B		Mean	249421.57	9475.915
		95% Confidence Interval for Mean	Lower Bound	230164.20
			Upper Bound	268678.95
		5% Trimmed Mean	245897.85	
		Median	244941.00	
		Variance	3142753517.782	
		Std. Deviation	56060.267	
		Minimum	169383	
		Maximum	406211	
		Range	236828	
		Interquartile Range	70834	
		Skewness	.779	.398
		Kurtosis	.793	.778



Tests of Normality

	Hasil	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
Pre	A	.130	35	.144	.932	35	.033
	B	.122	35	.200*	.943	35	.068
Post	A	.107	35	.200*	.939	35	.053
	B	.104	35	.200*	.949	35	.108

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Dari hasil uji normalitas didapatkan hasil uji Kolmogorov-Smirnov dengan nilai $p > 0,05$, maka distribusi data normal, sehingga dilakukan uji parametrik Independent T Test.

T-Test

Group Statistics

	Hasil	N	Mean	Std. Deviation	Std. Error Mean
Pre	A	35	233706.17	62596.973	10580.820
	B	35	249421.57	56060.267	9475.915
Post	A	35	233706.17	62596.973	10580.820
	B	35	249421.57	56060.267	9475.915

Independent Samples Test										
		Levene's Test for Equality of Variances				t-test for Equality of Means				
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
Pre	Equal variances assumed	.160	.691	-1.106	68	.272	-15715.400	14203.757	-44058.555	12627.755
	Equal variances not assumed			-1.106	67.189	.272	-15715.400	14203.757	-44064.749	12633.949
Post	Equal variances assumed	.160	.691	-1.106	68	.272	-15715.400	14203.757	-44058.555	12627.755
	Equal variances not assumed			-1.106	67.189	.272	-15715.400	14203.757	-44064.749	12633.949

Dari hasil uji Independent T Test, didapatkan :

Nilai $p > 0,05$ (0.272) untuk perbandingan krim A dan B (W0), sehingga disimpulkan tidak terdapat perbedaan kadar IL-12 yang bermakna setelah penggunaan krim A dan B sebelum 8 minggu.

Nilai $p > 0,05$ (0.272) untuk perbandingan krim A dan B (W8), sehingga disimpulkan tidak terdapat perbedaan kadar IL-12 yang bermakna setelah penggunaan krim A dan B setelah 8 minggu.

Perbandingan Penggunaan Krim A (W0) dan (W8)

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Pre Test	35	100.0%	0	0.0%	35	100.0%
Post Test	35	100.0%	0	0.0%	35	100.0%

Descriptives

		Statistic	Std. Error
Pre Test	Mean	253736.83	9778.303
	95% Confidence Interval for Mean	Lower Bound	233864.93
		Upper Bound	273608.73
	5% Trimmed Mean	249607.16	
	Median	240603.00	

	Variance		3346532022.08	
			7	
	Std. Deviation		57849.218	
	Minimum		172603	
	Maximum		432909	
	Range		260306	
	Interquartile Range		69098	
	Skewness		1.039	.398
	Kurtosis		1.502	.778
Post Test	Mean		257184.09	9335.636
	95% Confidence Interval for Mean	Lower Bound	238211.79	
		Upper Bound	276156.38	
	5% Trimmed Mean		253656.30	
	Median		246848.00	
	Variance		3050393428.61	
			0	
	Std. Deviation		55230.367	
	Minimum		181367	
	Maximum		407459	
	Range		226092	
	Interquartile Range		65638	
	Skewness		.800	.398
	Kurtosis		.602	.778

Tests of Normality

	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Pre Test	.130	35	.144	.932	35	.033
Post Test	.122	35	.200*	.943	35	.068

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Hasil uji normalitas menunjukkan nilai $p > 0,05$ pada uji Kolmogorov-Smirnov, maka distribusi data normal, sehingga dilakukan uji Paired Sample T Test.

T-Test

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Pre Test	253736.83	35	57849.218	9778.303
	Post Test	257184.09	35	55230.367	9335.636

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	Pre Test & Post Test	35	-.009	.961

Paired Samples Test										
		Paired Differences								
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig. (2-tailed)	
Pair 1	Pre Test - Post Test	-3447.257	80324.373	13577.297	Lower	Upper				
					-31039.645	24145.131	-.254	34	.801	

Berdasarkan uji Paired Sample T Test, didapatkan nilai $p > 0,05$ (0.801), maka dapat disimpulkan tidak terdapat perbedaan kadar IL-12 yang bermakna sebelum (W0) dan sesudah (W8) penggunaan krim A.

Perbandingan Penggunaan Krim B (H0) dan (H5)

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Pre	35	100.0%	0	0.0%	35	100.0%
Post	35	100.0%	0	0.0%	35	100.0%

Descriptives

		Statistic	Std. Error
Pre	Mean	233706.17	10580.820
	95% Confidence Interval for Lower Bound	212203.36	

	Mean	Upper Bound	255208.98	
	5% Trimmed Mean		229655.36	
	Median		231192.00	
	Variance		3918381076.323	
	Std. Deviation		62596.973	
	Minimum		136725	
	Maximum		421872	
	Range		285147	
	Interquartile Range		81043	
	Skewness		.943	.398
	Kurtosis		1.509	.778
Post	Mean		249421.57	9475.915
	95% Confidence Interval for	Lower Bound	230164.20	
	Mean	Upper Bound	268678.95	
	5% Trimmed Mean		245897.85	
	Median		244941.00	
	Variance		3142753517.782	
	Std. Deviation		56060.267	
	Minimum		169383	
	Maximum		406211	
	Range		236828	
	Interquartile Range		70834	
	Skewness		.779	.398
	Kurtosis		.793	.778

Tests of Normality

	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Pre	.107	35	.200*	.939	35	.053
Post	.104	35	.200*	.949	35	.108

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Hasil uji normalitas menunjukkan nilai $p > 0,05$ pada uji Kolomogorv-Smirnof, maka distribusi data normal, sehingga dilakukan uji Paired Sample T test.

T-Test

Paired Samples Statistics

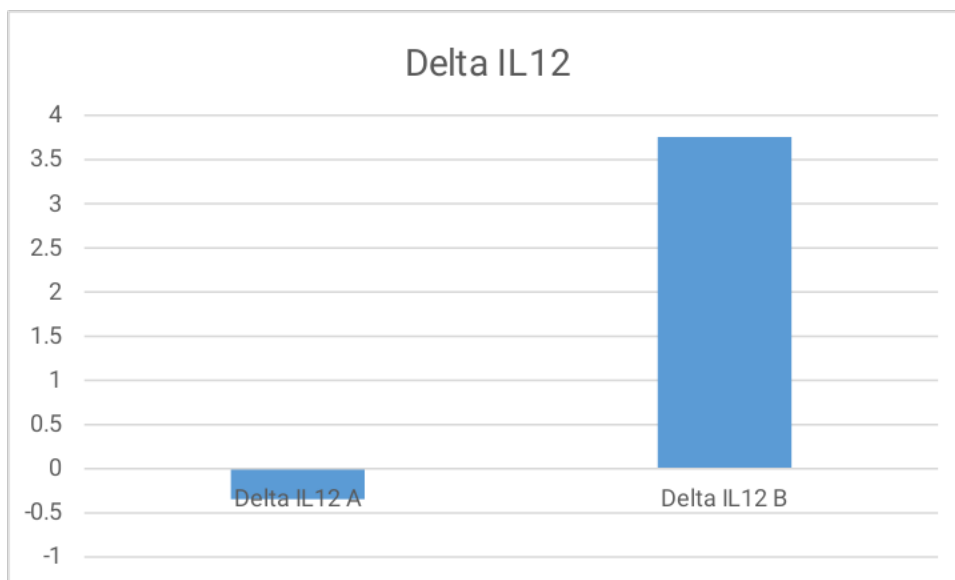
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Pre	233706.17	35	62596.973	10580.820
	Post	249421.57	35	56060.267	9475.915

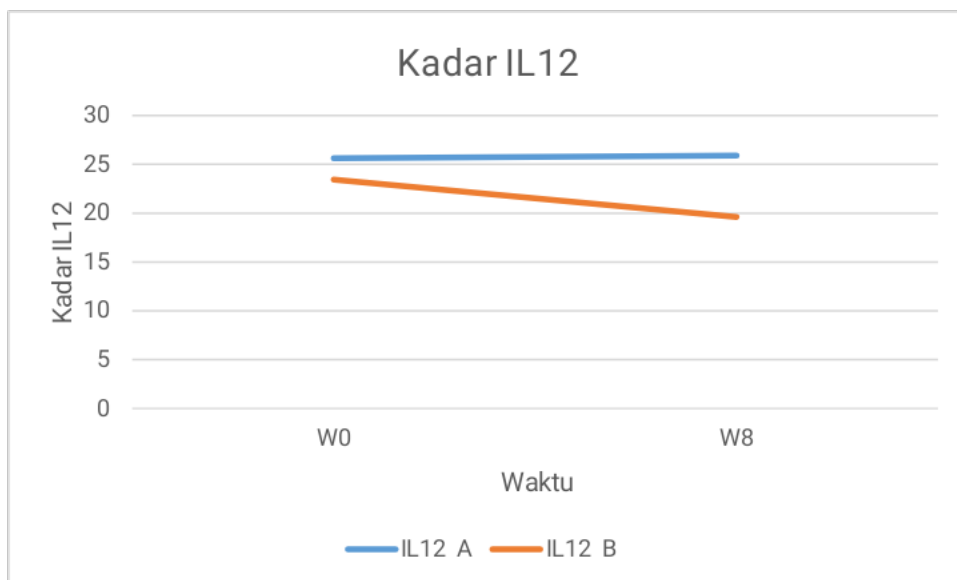
Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	Pre & Post	35	-.105	.550

		Paired Samples Test							
		Paired Differences							
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig. (2-tailed)
					Lower	Upper			
Pair 1	Pre - Post	-15715.400	88289.871	14923.712	-46044.032	14613.232	-1.053	34	.300

Berdasarkan uji Paired Sample T Test, didapatkan nilai $p > 0,05$ (0,300), maka dapat disimpulkan tidak terdapat perbedaan kadar IL-12 sebelum (W0) dan sesudah (W8) penggunaan krim B.





Uji Kolerasi Antara IL12 dengan nilai Sebumeter

Uji kolerasi dilakukan dengan Uji Spearman, didapatkan beberapa data distribusi tidak normal $p > 0.05$

			IL12 W0 A	Sebumeter Dahi W0 A	Sebumeter Pipi W0 A
Spearman's rho	IL12 W0 A	Correlation Coefficient	1.000	.177	.243
		Sig. (2-tailed)	.	.308	.160
		N	35	35	35

Correlations

			IL12 W8 A	Sebumeter Dahi W8 A	Sebumeter Pipi W8 A
Spearman's rho	IL12 W8 A	Correlation Coefficient	1.000	.039	-.242

		Sig. (2-tailed)	.	.825	.161
		N	35	35	35

Pada uji kolerasi Spearman antara kadar IL-12 dengan nilai sebumeter sesudah dan sebelum perlakuan pada dahi dan pipi didapatkan $p > 0.05$. Tidak didapatkan adanya kolerasi antara kadar IL12 dan nilai sebumeter pada dahi dan pipi pada pemberian topical A.

Correlations

			IL12 W0 B	Sebumeter Dahi W0 B	Sebumeter Pipi W0 B
Spearman's rho	IL12 W0 B	Correlation Coefficient	1.000	.095	.129
		Sig. (2-tailed)	.	.586	.460
		N	35	35	35

			IL12 W8 B	Sebumeter Dahi W8 B	Sebumeter Pipi W8 B
Spearman's rho	IL12 W8 B	Correlation Coefficient	1.000	.016	-.022
		Sig. (2-tailed)	.	.929	.899
		N	35	35	35

Pada uji kolerasi Spearman antara kadar IL-12 dengan nilai sebumeter sesudah dan sebelum perlakuan pada dahi dan pipi didapatkan $p > 0.05$. Tidak didapatkan adanya kolerasi antara kadar IL12 dan nilai sebumeter pada dahi dan pipi pada pemberian topical B.



