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LAMPIRAN

Lampiran 1. Persetujuan etik penelitian

KEMENTERIAN PENDIDIKAN, KEBUDAYAAN, RISET DAN TEKNOLOGI
UNIVERSITAS HASANUDDIN FAKULTAS KEDOKTERAN
KOMITE ETIK PENELITIAN KESEHATAN
RSPTN UNIVERSITAS HASANUDDIN
RSUP Dr. WAHIDIN SUDIROHUSODO MAKASSAR
Sekretariat : Lantai 2 Gedung Laboratorium Terpadu
JL.PERINTIS KEMERDEKAAN KAMPUS TAMALANREA KM.10 MAKASSAR 90245.
Contact Person: dr. Agussalim Bukhari.,MMed.PhD. SpGK TELP. 081241850858, 0411 5780103, Fax : 0411-581431

REKOMENDASI PERSETUJUAN ETIK
Nomor : 47/UN4.6.4.5.31/ PP36/ 2022

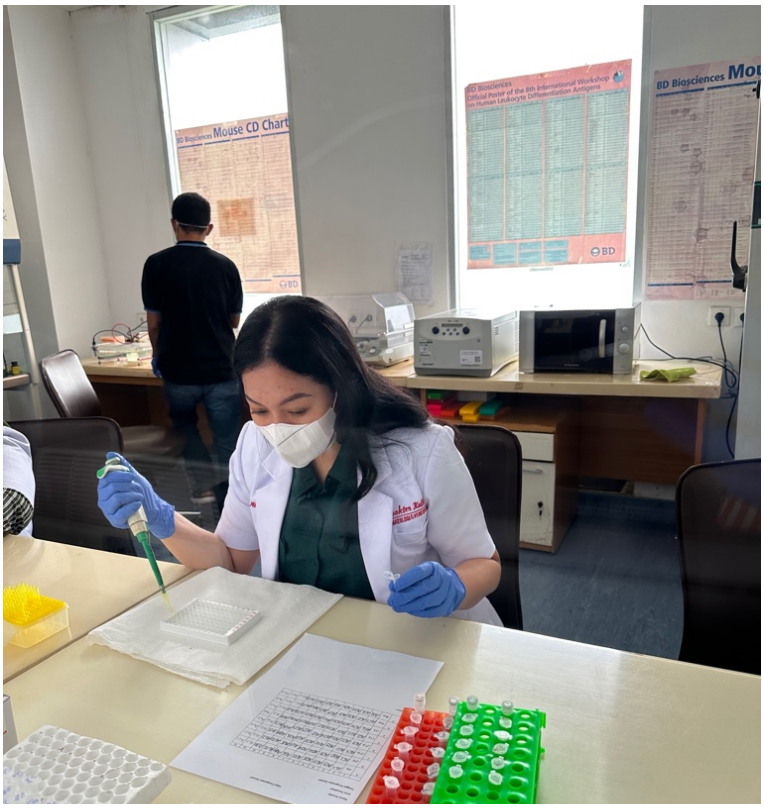
Tanggal: 31 Januari 2022

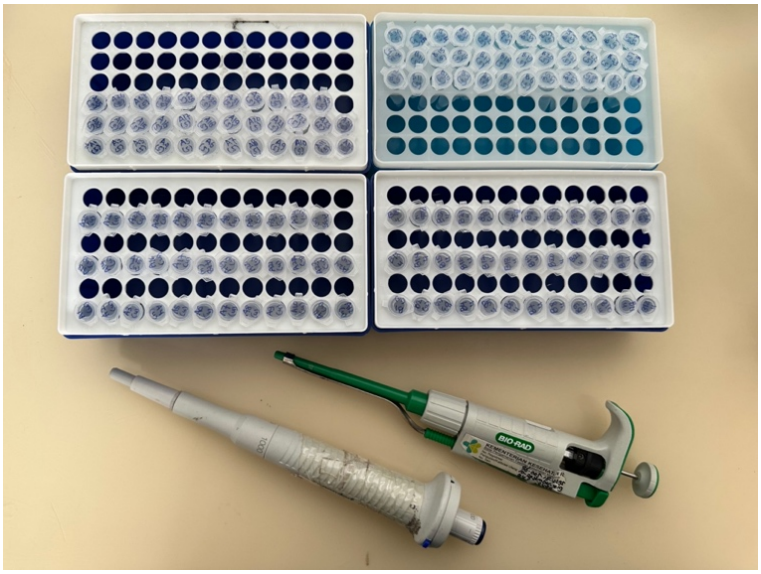
Dengan ini Menyatakan bahwa Protokol dan Dokumen yang Berhubungan Dengan Protokol berikut ini telah mendapatkan Persetujuan Etik :

No Protokol	UH22010004	No Sponsor Protokol	
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	☐ Exempted ☐ Expedited ☒ Fullboard Tanggal **18 Januari 2022**	Masa Berlaku **31 Januari 2022** sampai **31 Januari 2023**	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 Bukhari, M.Med.,Ph.D.,Sp.GK (K)**	Tanda tangan	

Kewajiban Peneliti Utama:
- Menyerahkan Amandemen Protokol untuk persetujuan sebelum di implementasikan
- Menyerahkan Laporan SAE ke Komisi Etik dalam 24 Jam dan dilengkapi dalam 7 hari dan Lapor 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 prokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan

Lampiran 2. Alat dan Bahan


BD Biosciences Mouse CD Chart
BD Biosciences
Official Poster of the 8th International Workshop
on Human Leukocyte Differentiation Antigens
BD


BIO-RAD

Lampiran 3. *Inform Consent* dan Kuisioner Penelitian

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 5% Terhadap Perbaikan Klinis dan Kadar IL 10 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,

(.....)

Kode Penelitian:

KUISIONER 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 4. Data SPSS

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Lesi NI A H0	35	100.0%	0	0.0%	35	100.0%
Lesi NI A H2	35	100.0%	0	0.0%	35	100.0%
Lesi NI A H4	35	100.0%	0	0.0%	35	100.0%
Lesi NI A H6	35	100.0%	0	0.0%	35	100.0%
Lesi NI A H8	35	100.0%	0	0.0%	35	100.0%
Lesi I A H0	35	100.0%	0	0.0%	35	100.0%
Lesi I A H2	35	100.0%	0	0.0%	35	100.0%
Lesi I A H4	35	100.0%	0	0.0%	35	100.0%
Lesi I A H6	35	100.0%	0	0.0%	35	100.0%
Lesi I A H8	35	100.0%	0	0.0%	35	100.0%
Lesi NI B H0	35	100.0%	0	0.0%	35	100.0%
Lesi NI B H2	35	100.0%	0	0.0%	35	100.0%
Lesi NI B H4	35	100.0%	0	0.0%	35	100.0%
Lesi NI B H6	35	100.0%	0	0.0%	35	100.0%
Lesi NI B H8	35	100.0%	0	0.0%	35	100.0%
Lesi I B H0	35	100.0%	0	0.0%	35	100.0%
Lesi I B H2	35	100.0%	0	0.0%	35	100.0%
Lesi I B H4	35	100.0%	0	0.0%	35	100.0%
Lesi I B H6	35	100.0%	0	0.0%	35	100.0%
Lesi I B H8	35	100.0%	0	0.0%	35	100.0%

	Median		3.00	
	Variance		26.718	
	Std. Deviation		5.169	
	Minimum		0	
	Maximum		20	
	Range		20	
	Interquartile Range		7	
	Skewness		1.402	.398
	Kurtosis		1.708	.778
Lesi I B H8	Mean		3.20	.825
	95% Confidence Interval for Mean	Lower Bound	1.52	
		Upper Bound	4.88	
	5% Trimmed Mean		2.54	
	Median		1.00	
	Variance		23.812	
	Std. Deviation		4.880	
	Minimum		0	
	Maximum		20	
	Range		20	
	Interquartile Range		6	
	Skewness		1.953	.398
	Kurtosis		3.842	.778

Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Lesi NI A H0	.165	35	.017	.897	35	.003
Lesi NI A H2	.140	35	.079	.908	35	.007
Lesi NI A H4	.156	35	.030	.905	35	.005
Lesi NI A H6	.202	35	.001	.840	35	.000
Lesi NI A H8	.198	35	.001	.807	35	.000
Lesi I A H0	.163	35	.019	.917	35	.012
Lesi I A H2	.312	35	.000	.669	35	.000
Lesi I A H4	.201	35	.001	.803	35	.000
Lesi I A H6	.225	35	.000	.728	35	.000
Lesi I A H8	.202	35	.001	.786	35	.000
Lesi NI B H0	.160	35	.024	.879	35	.001
Lesi NI B H2	.124	35	.188	.958	35	.200
Lesi NI B H4	.121	35	.200*	.922	35	.017
Lesi NI B H6	.139	35	.085	.964	35	.299
Lesi NI B H8	.102	35	.200*	.952	35	.130
Lesi I B H0	.213	35	.000	.734	35	.000
Lesi I B H2	.189	35	.003	.830	35	.000
Lesi I B H4	.169	35	.012	.852	35	.000
Lesi I B H6	.187	35	.003	.832	35	.000
Lesi I B H8	.256	35	.000	.714	35	.000

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

a. Lilliefors Significance Correction

P<0.05 → Distribus tidak normal → Uji non Parametrik Friedman

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
Lesi NI A H0	35	65.03	27.493	22	120
Lesi NI A H2	35	58.60	35.552	13	162
Lesi NI A H4	35	55.17	33.514	13	160
Lesi NI A H6	35	51.43	29.043	14	143
Lesi NI A H8	35	50.34	30.501	14	142

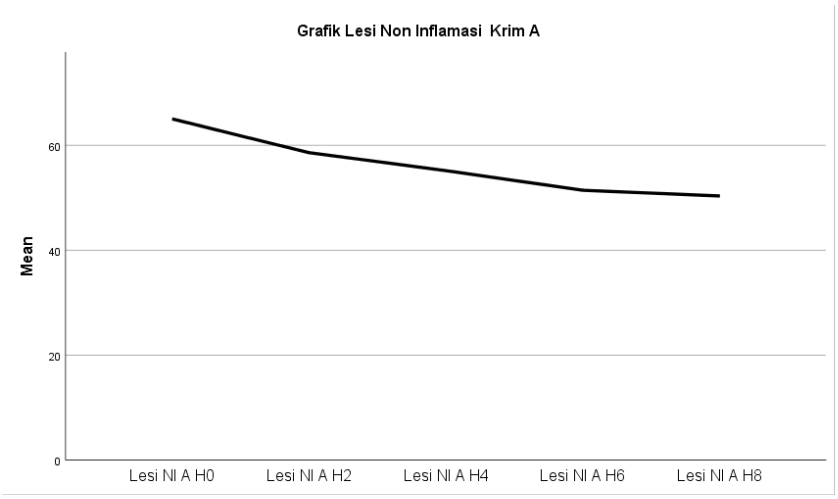
Ranks

	Mean Rank
Lesi NI A H0	3.73
Lesi NI A H2	3.11
Lesi NI A H4	2.91
Lesi NI A H6	2.71
Lesi NI A H8	2.53

Test Statistics[a]

N	35
Chi-Square	12.127
df	4
Asymp. Sig.	.016

a. Friedman Test



Uji Friedman pada total lesi inflamasi terdapat perbedaan signifikan secara statistic pada penggunaan krim A dimana p<0.05 (p=0.00)

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
Lesi NI B H0	35	66.31	30.256	29	148
Lesi NI B H2	35	61.94	26.231	20	133
Lesi NI B H4	35	45.86	21.546	17	96
Lesi NI B H6	35	36.31	16.022	8	71
Lesi NI B H8	35	31.69	16.376	4	81

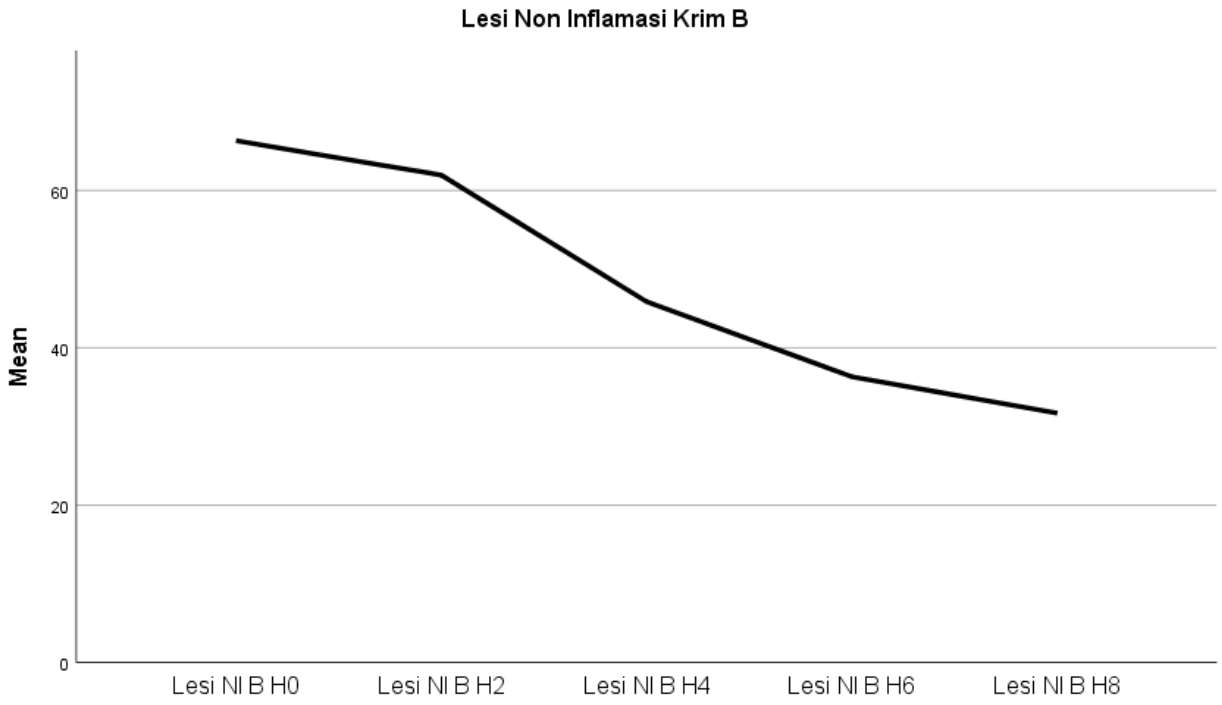
Ranks

	Mean Rank
Lesi NI B H0	4.21
Lesi NI B H2	4.00
Lesi NI B H4	3.09
Lesi NI B H6	2.09
Lesi NI B H8	1.61

Test Statistics[a]

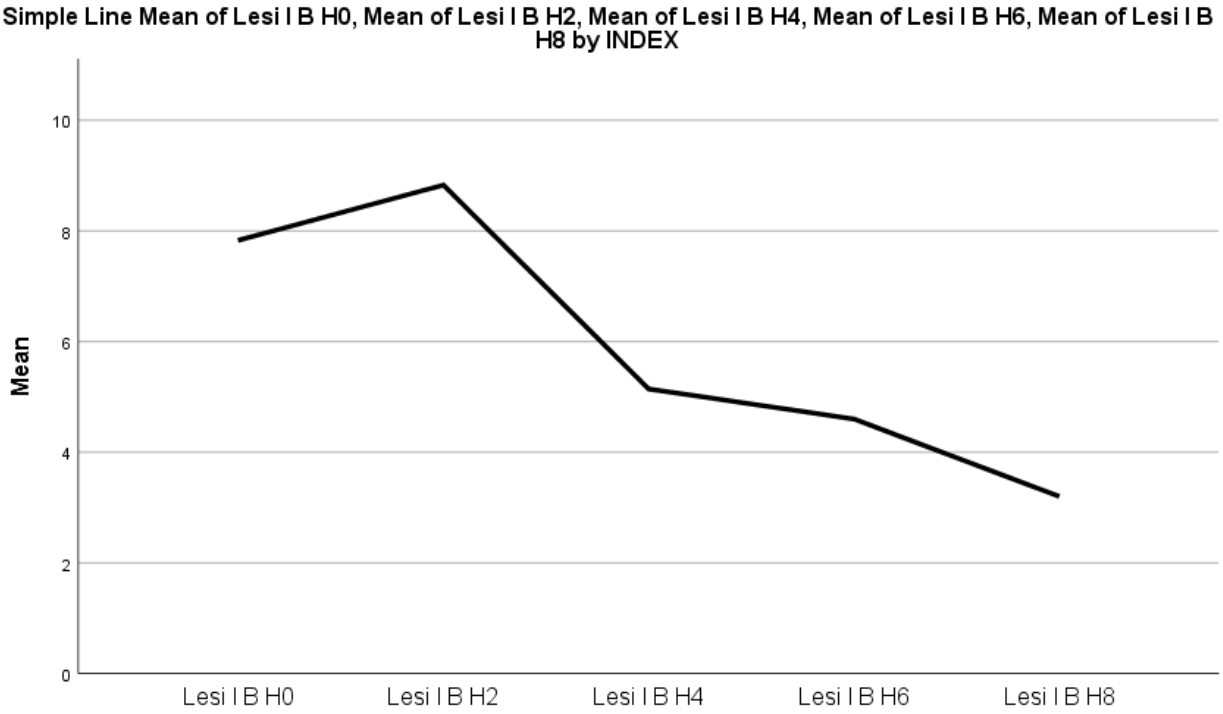
N	35
Chi-Square	74.828
df	4
Asymp. Sig.	.000

a. Friedman Test



Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
Lesi I B H0	35	7.83	7.322	2	39
Lesi I B H2	35	8.83	9.067	0	40
Lesi I B H4	35	5.14	5.370	0	19
Lesi I B H6	35	4.60	5.169	0	20
Lesi I B H8	35	3.20	4.880	0	20



Case Processing Summary

		Cases					
		Valid		Missing		Total	
	Kelompok	N	Percent	N	Percent	N	Percent
Lesi NI AB H0	Krim A	35	100.0%	0	0.0%	35	100.0%
	Krim B	35	100.0%	0	0.0%	35	100.0%
Lesi NI AB H2	Krim A	35	100.0%	0	0.0%	35	100.0%
	Krim B	35	100.0%	0	0.0%	35	100.0%
Lesi NI AB H4	Krim A	35	100.0%	0	0.0%	35	100.0%
	Krim B	35	100.0%	0	0.0%	35	100.0%
Lesi NI AB H6	Krim A	35	100.0%	0	0.0%	35	100.0%
	Krim B	35	100.0%	0	0.0%	35	100.0%
Lesi NI AB H8	Krim A	35	100.0%	0	0.0%	35	100.0%
	Krim B	35	100.0%	0	0.0%	35	100.0%
Lesi I AB H0	Krim A	35	100.0%	0	0.0%	35	100.0%
	Krim B	35	100.0%	0	0.0%	35	100.0%

Lesi I AB H2	Krim A	35	100.0%	0	0.0%	35	100.0%
	Krim B	35	100.0%	0	0.0%	35	100.0%
Lesi I AB H4	Krim A	35	100.0%	0	0.0%	35	100.0%
	Krim B	35	100.0%	0	0.0%	35	100.0%
Lesi I AB H6	Krim A	35	100.0%	0	0.0%	35	100.0%
	Krim B	35	100.0%	0	0.0%	35	100.0%
Lesi I AB H8	Krim A	35	100.0%	0	0.0%	35	100.0%
	Krim B	35	100.0%	0	0.0%	35	100.0%

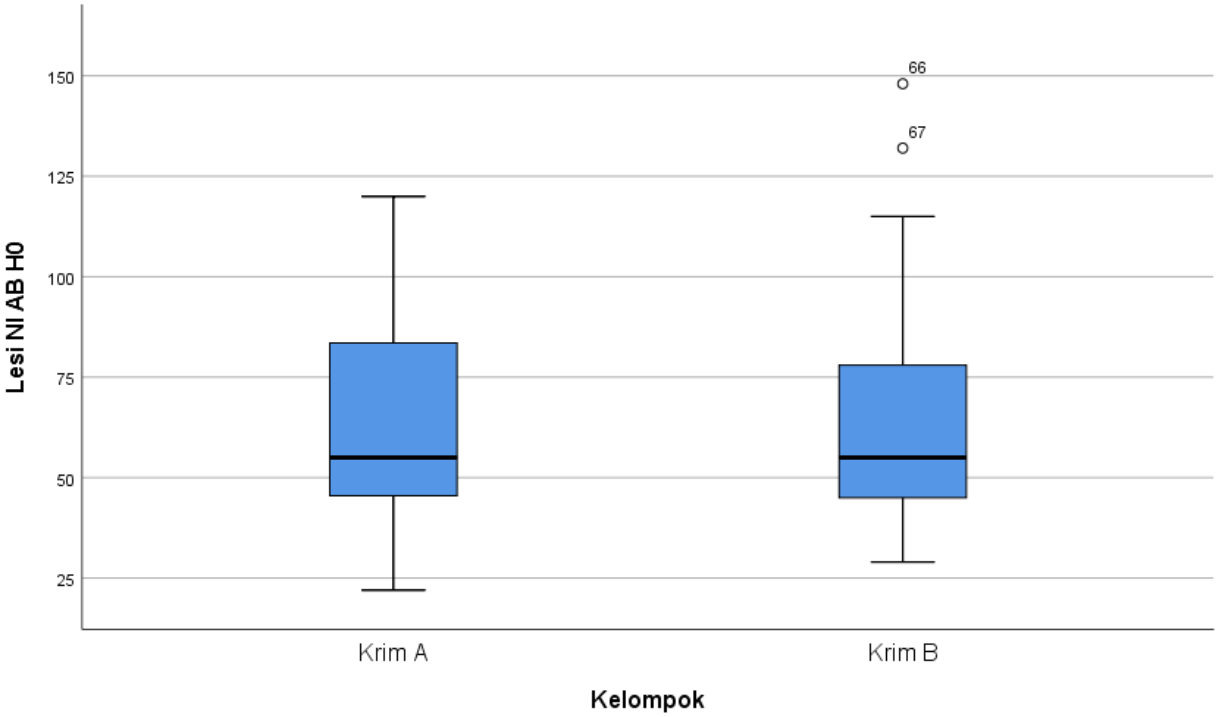
Tests of Normality

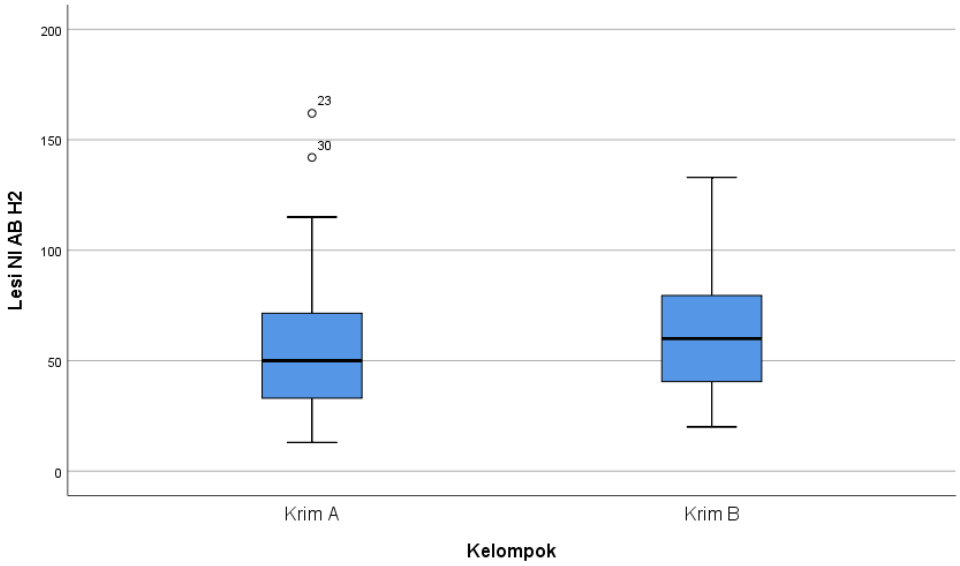
		Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Kelompok	Statistic	df	Sig.	Statistic	df	Sig.
Lesi NI AB H0	Krim A	.165	35	.017	.897	35	.003
	Krim B	.160	35	.024	.879	35	.001
Lesi NI AB H2	Krim A	.140	35	.079	.908	35	.007
	Krim B	.124	35	.188	.958	35	.200
Lesi NI AB H4	Krim A	.156	35	.030	.905	35	.005
	Krim B	.121	35	.200*	.922	35	.017
Lesi NI AB H6	Krim A	.202	35	.001	.840	35	.000
	Krim B	.139	35	.085	.964	35	.299
Lesi NI AB H8	Krim A	.198	35	.001	.807	35	.000
	Krim B	.102	35	.200*	.952	35	.130
Lesi I AB H0	Krim A	.163	35	.019	.917	35	.012
	Krim B	.213	35	.000	.734	35	.000
Lesi I AB H2	Krim A	.312	35	.000	.669	35	.000
	Krim B	.189	35	.003	.830	35	.000
Lesi I AB H4	Krim A	.201	35	.001	.803	35	.000
	Krim B	.169	35	.012	.852	35	.000
Lesi I AB H6	Krim A	.225	35	.000	.728	35	.000

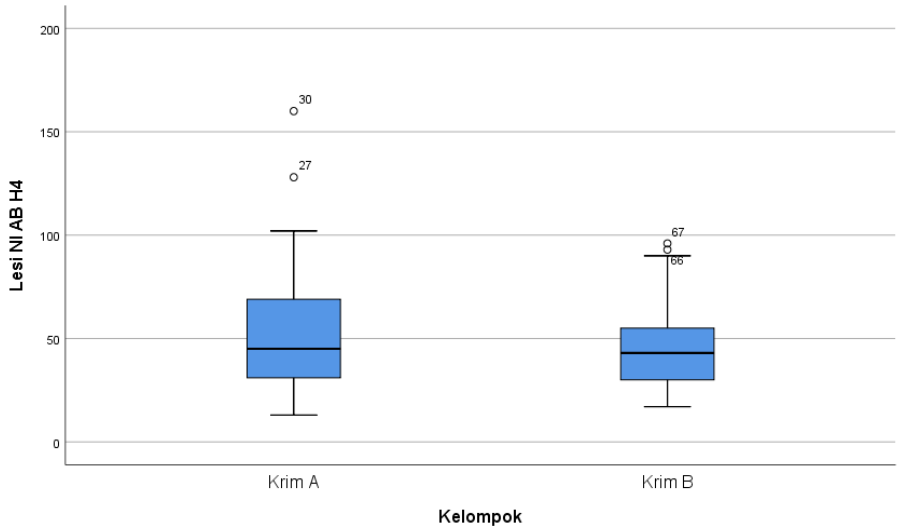
	Krim B	.187	35	.003	.832	35	.000
Lesi I AB H8	Krim A	.202	35	.001	.786	35	.000
	Krim B	.256	35	.000	.714	35	.000

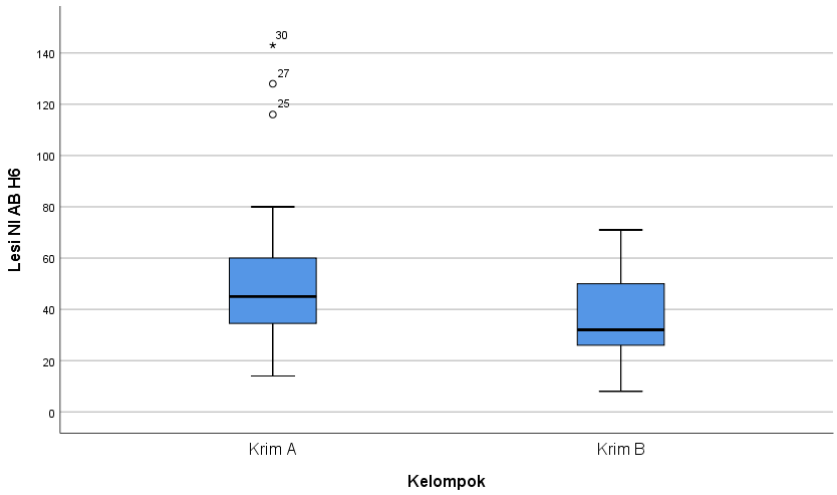
*. This is a lower bound of the true significance.

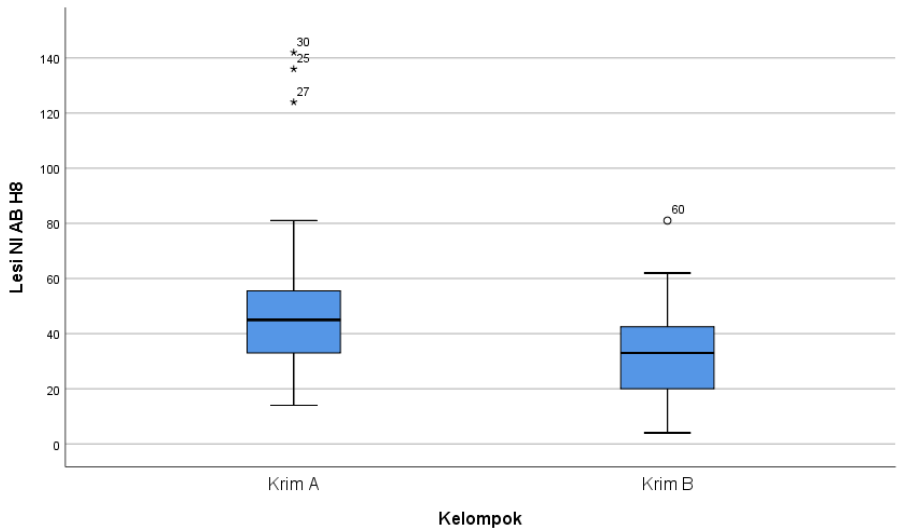
a. Lilliefors Significance Correction






Lesi NI AB H4
200
150
100
50
0
30
27
67
66
Krim A
Krim B
Kelompok


Lesi NI AB H6
140
120
100
80
60
40
20
0
30
27
25
Krim A
Krim B
Kelompok


Lesi NI AB H8
140
120
100
80
60
40
20
0
30
25
27
60
Krim A
Krim B
Kelompok

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
Lesi NI AB H0	70	65.67	28.704	22	148
Lesi NI AB H2	70	60.27	31.060	13	162
Lesi NI AB H4	70	50.51	28.359	13	160
Lesi NI AB H6	70	43.87	24.496	8	143
Lesi NI AB H8	70	41.01	26.054	4	142
Kelompok	70	1.50	.504	1	2

Mann-Whitney Test

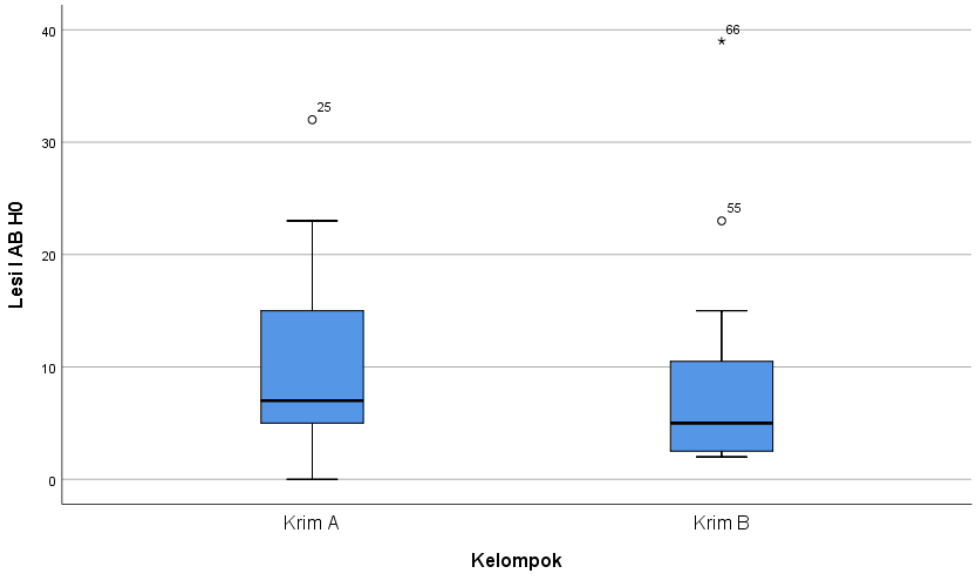
Ranks

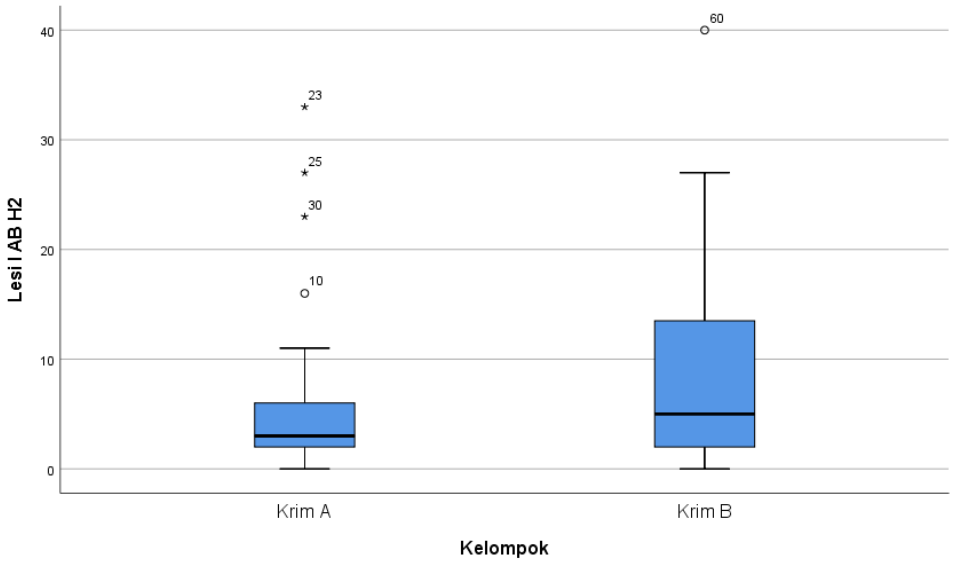
	Kelompok	N	Mean Rank	Sum of Ranks
Lesi NI AB H0	Krim A	35	35.57	1245.00
	Krim B	35	35.43	1240.00
	Total	70		
Lesi NI AB H2	Krim A	35	32.91	1152.00
	Krim B	35	38.09	1333.00
	Total	70		
Lesi NI AB H4	Krim A	35	37.73	1320.50
	Krim B	35	33.27	1164.50
	Total	70		
Lesi NI AB H6	Krim A	35	41.39	1448.50
	Krim B	35	29.61	1036.50
	Total	70		
Lesi NI AB H8	Krim A	35	42.97	1504.00
	Krim B	35	28.03	981.00
	Total	70		

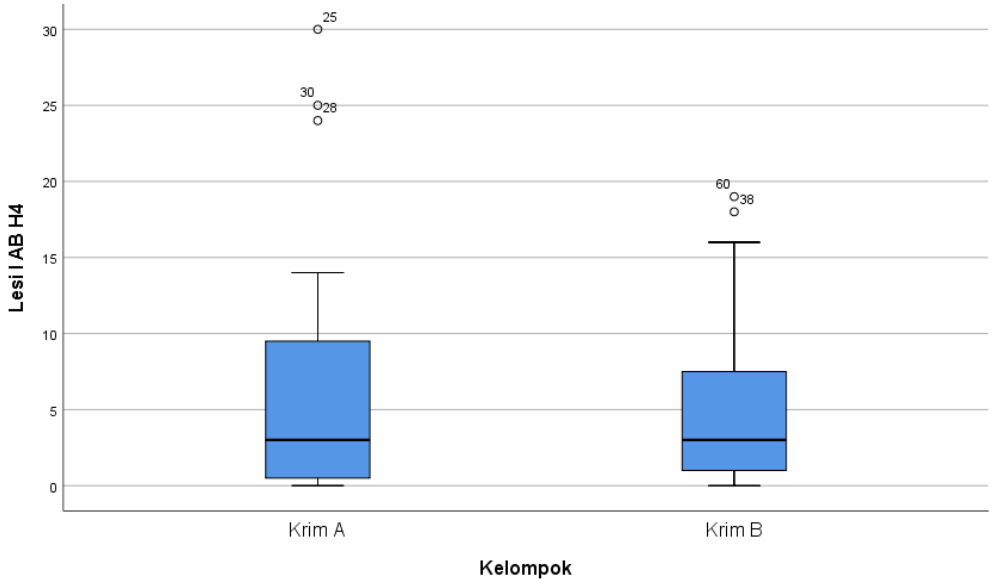
Test Statistics[a]

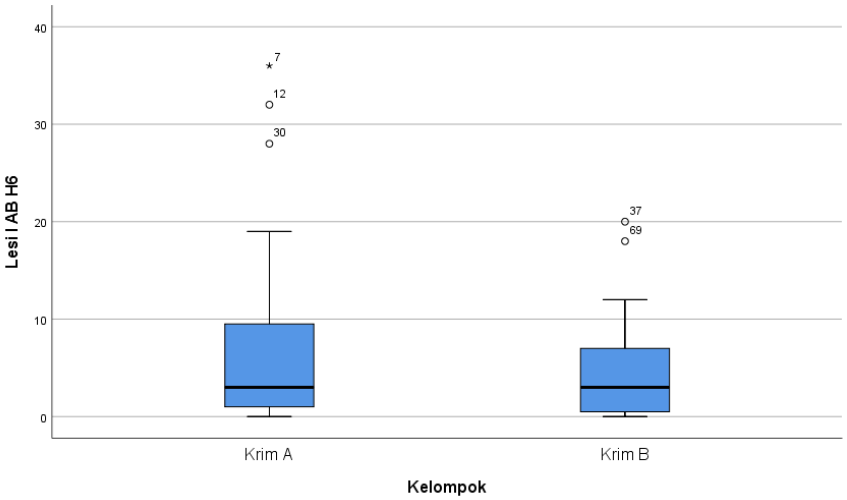
	Lesi NI AB H0	Lesi NI AB H2	Lesi NI AB H4	Lesi NI AB H6	Lesi NI AB H8
Mann-Whitney U	610.000	522.000	534.500	406.500	351.000
Wilcoxon W	1240.000	1152.000	1164.500	1036.500	981.000
Z	-.029	-1.063	-.916	-2.422	-3.074
Asymp. Sig. (2-tailed)	.977	.288	.359	**.015**	**.002**

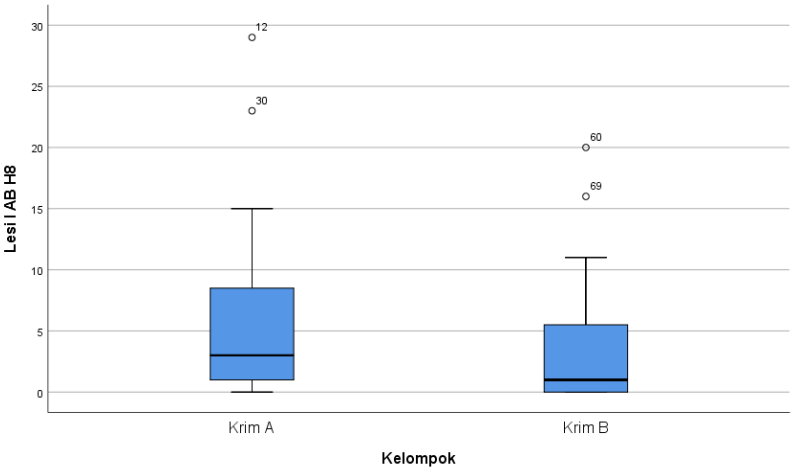
a. Grouping Variable: Kelompok






Lesi I AB H4
30
25
20
15
10
5
0
25
30
28
60
38
Krim A
Krim B
Kelompok


Lesi I AB H6
40
30
20
10
0
7
12
30
37
69
Krim A
Krim B
Kelompok


Lesi I AB H8
30
25
20
15
10
5
0
12
30
60
69
Krim A
Krim B
Kelompok

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
Lesi I AB H0	70	8.79	7.425	0	39
Lesi I AB H2	70	7.26	8.500	0	40
Lesi I AB H4	70	5.80	6.617	0	30
Lesi I AB H6	70	5.74	7.415	0	36
Lesi I AB H8	70	4.49	6.050	0	29
Kelompok	70	1.50	.504	1	2

Mann-Whitney Test

Ranks

	Kelompok	N	Mean Rank	Sum of Ranks
Lesi I AB H0	Krim A	35	38.70	1354.50
	Krim B	35	32.30	1130.50
	Total	70		
Lesi I AB H2	Krim A	35	31.29	1095.00
	Krim B	35	39.71	1390.00
	Total	70		
Lesi I AB H4	Krim A	35	35.94	1258.00
	Krim B	35	35.06	1227.00
	Total	70		
Lesi I AB H6	Krim A	35	37.31	1306.00
	Krim B	35	33.69	1179.00
	Total	70		
Lesi I AB H8	Krim A	35	41.14	1440.00
	Krim B	35	29.86	1045.00
	Total	70		

Test Statistics[a]

	Lesi NI A W2 - Lesi NI A W0	Lesi NI A W4 - Lesi NI A W0	Lesi NI A W6 - Lesi NI A W0	Lesi NI A W8 - Lesi NI A W0	Lesi NI A W4 - Lesi NI A W2	Lesi NI A W6 - Lesi NI A W2	Lesi NI A W8 - Lesi NI A W2	Lesi NI A W6 - Lesi NI A W4	Lesi NI A W8 - Lesi NI A W4	Lesi NI A W8 - Lesi NI A W6
Z	-1.753[b]	-2.253[b]	-2.834[b]	-2.727[b]	-.787[b]	-1.262[b]	-1.758[b]	-1.240[b]	-1.196[b]	-1.095[b]
Asymp. Sig. (2-tailed)	.080	**.024**	**.005**	**.006**	.431	.207	.079	.215	.232	.274

a. Wilcoxon Signed Ranks Test

b. Based on positive ranks.

Test Statistics[a]

	Lesi I AB H0	Lesi I AB H2	Lesi I AB H4	Lesi I AB H6	Lesi I AB H8
Mann-Whitney U	500.500	465.000	597.000	549.000	415.000
Wilcoxon W	1130.500	1095.000	1227.000	1179.000	1045.000
Z	-1.321	-1.740	-.183	-.752	-2.362
Asymp. Sig. (2-tailed)	.186	.082	.854	.452	**.018**

a. Grouping Variable: Kelompok

z. Lesi NI A W8 > Lesi NI A W4

aa. Lesi NI A W8 = Lesi NI A W4

ab. Lesi NI A W8 < Lesi NI A W6

ac. Lesi NI A W8 > Lesi NI A W6

ad. Lesi NI A W8 = Lesi NI A W6

Ranks

		N	Mean Rank	Sum of Ranks
Lesi I A W2 - Lesi I A W0	Negative Ranks	28[a]	19.05	533.50
	Positive Ranks	7[b]	13.79	96.50
	Ties	0[c]		
	Total	35		
Lesi I A W4 - Lesi I A W0	Negative Ranks	28[d]	17.54	491.00
	Positive Ranks	6[e]	17.33	104.00

	Ties	1[f]		
	Total	35		
Lesi I A W6 - Lesi I A W0	Negative Ranks	22[g]	17.09	376.00
	Positive Ranks	10[h]	15.20	152.00
	Ties	3[i]		
	Total	35		
Lesi I A W8 - Lesi I A W0	Negative Ranks	27[j]	16.78	453.00
	Positive Ranks	6[k]	18.00	108.00
	Ties	2[l]		
	Total	35		

a. Lesi I A W2 < Lesi I A W0

b. Lesi I A W2 > Lesi I A W0

c. Lesi I A W2 = Lesi I A W0

d. Lesi I A W4 < Lesi I A W0

e. Lesi I A W4 > Lesi I A W0

f. Lesi I A W4 = Lesi I A W0

g. Lesi I A W6 < Lesi I A W0

h. Lesi I A W6 > Lesi I A W0

i. Lesi I A W6 = Lesi I A W0

j. Lesi I A W8 < Lesi I A W0

k. Lesi I A W8 > Lesi I A W0

l. Lesi I A W8 = Lesi I A W0

Test Statistics[a]

	Lesi I A W2 - Lesi I A W0	Lesi I A W4 - Lesi I A W0	Lesi I A W6 - Lesi I A W0	Lesi I A W8 - Lesi I A W0
Z	-3.585[b]	-3.313[b]	-2.098[b]	-3.088[b]
Asymp. Sig. (2-tailed)	**.000**	**.001**	**.036**	**.002**

a. Wilcoxon Signed Ranks Test

b. Based on positive ranks.