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LAMPIRAN 1 Surat Rekomendasi Etik

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

REKOMENDASI PERSETUJUAN ETIK
Nomor : 505/UN4.6.4.5.31/ PP36/ 2023

Tanggal: 24 Juli 2023

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

No Protokol	UH23040217	No Sponsor	
Peneliti Utama	**dr. Nurussyariah, M.AppSci, Sp.N(K)**	Sponsor	
Judul Peneliti	Luaran Klinis Nyeri Radikular Lumbosakral Kronik Setelah Pemberian Triamsinolon Epidural: Analisis Kadar High Mobility Group Box-1 dan NGF Serum		
No Versi Protokol	2	Tanggal Versi	**17 Juli 2023**
No Versi PSP	2	Tanggal Versi	**17 Juli 2023**
Tempat Penelitian	RSUP Dr. Wahidin Sudirohusodo dan RS Jejaring Makassar		
Jenis Review	☐ Exempted ☐ Expedited ☒ Fullboard Tanggal **17 Mei 2023**	Masa Berlaku **24 Juli 2023** sampai **24 Juli 2024**	Frekuensi review lanjutan
Ketua KEP Universitas Hasanuddin	Nama **Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K)**	Tanda tangan	
Sekretaris KEP Universitas Hasanuddin	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
- erahkan laporan akhir setelah Penelitian berakhir
- orkan penyimpangan dari prokol yang disetujui (protocol deviation / violation)
- atuhi semua peraturan yang ditentukan

KEMENTERIAN PENDIDIKAN, KEBUDAYAAN, RISET DAN TEKNOLOGI
UNIVERSITAS HASANUDDIN
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SURAT PERSETUJUAN

Yang bertanda tangan dibawah ini :

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Menyetujui mahasiswa tersebut dibawah ini :

N a m a : **Nurussyariah**
Nomor Pokok : C013201017
Program Studi : Doktor Ilmu Kedokteran
Judul Penelitian :
LUARAN KLINIS NYERI RADIKULAR LUMBOSAKRAL KRONIK SETELAH PEMBERIAN TRIAMSINOLON EPIDURAL: ANALISIS KADAR HIGH MOBILITY GROUP BOX-1 dan NGF SERUM

Makassar, 8 Agustus 2022
Ketua Program Studi S3
Ilmu Kedokteran

Dr. dr. Irfan Idris, M.Kes
NIP. 196711031998021001

LAMPIRAN 2 Uji Statistik

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REGRESSION
  /SELECT=GrupKode EQ 1
  /MISSING LISTWISE
  /STATISTICS COEFF OUTS R ANOVA
  /CRITERIA=PIN(.05) POUT(.10)
  /NOORIGIN
  /DEPENDENT DeltaNPRS
  /METHOD=ENTER DeltaHMGB DeltaNGF.
```

Regression

Notes

Output Created		19-OCT-2023 21:08:35
Comments		
Input	Data	C:\Users\LENOVO\Desktop\HMGB-1\HASIL\Statistik\Hasil_S3.sav
	Active Dataset	DataSet1
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	57
Missing Value Handling	Definition of Missing	User-defined missing values are treated as missing.
	Cases Used	Statistics are based on cases with no missing values for any variable used.
Syntax		REGRESSION /SELECT=GrupKode EQ 1 /MISSING LISTWISE /STATISTICS COEFF OUTS R ANOVA /CRITERIA=PIN(.05) POUT(.10) /NOORIGIN /DEPENDENT DeltaNPRS /METHOD=ENTER DeltaHMGB DeltaNGF.

Resources	Processor Time	00:00:00,00
	Elapsed Time	00:00:00,01
	Memory Required	4176 bytes
	Additional Memory Required for Residual Plots	0 bytes

Variables Entered/Removed[a,b]

Model	Variables Entered	Variables Removed	Method
1	DeltaNGF, Delta HMGB1[c]	.	Enter

a. Dependent Variable: Delta Skala Nyeri

b. Models are based only on cases for which Kelompok Sampel = Intervensi

c. All requested variables entered.

Model Summary

Model	R Kelompok Sampel = Intervensi (Selected)	R Square	Adjusted R Square	Std. Error of the Estimate
1	.552[a]	.304	.263	1.193

a. Predictors: (Constant), DeltaNGF, Delta HMGB1

ANOVA[a,b]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	21.168	2	10.584	7.435	.002[c]
	Residual	48.400	34	1.424		
	Total	69.568	36			

a. Dependent Variable: Delta Skala Nyeri

b. Selecting only cases for which Kelompok Sampel = Intervensi

c. Predictors: (Constant), DeltaNGF, Delta HMGB1

Coefficients[a,b]

	Unstandardized Coefficients	Standardized Coefficients	t	Sig.

		B	Std. Error	Beta		
1	(Constant)	1.604	.252		6.356	.000
	Delta HMGB1	.000	.000	.123	.853	.400
	DeltaNGF	.253	.066	.557	3.847	.001

a. Dependent Variable: Delta Skala Nyeri

b. Selecting only cases for which Kelompok Sampel = Intervensi

```
REGRESSION
  /SELECT=GrupKode EQ 2
  /MISSING LISTWISE
  /STATISTICS COEFF OUTS R ANOVA
  /CRITERIA=PIN(.05) POUT(.10)
  /NOORIGIN
  /DEPENDENT DeltaNPRS
  /METHOD=ENTER DeltaHMGB DeltaNGF.
```

Regression

Variables Entered/Removed[a,b]

Model	Variables Entered	Variables Removed	Method
1	DeltaNGF, Delta HMGB1[c]	.	Enter

a. Dependent Variable: Delta Skala Nyeri

b. Models are based only on cases for which Kelompok Sampel = Kontrol

c. All requested variables entered.

Variables Entered/Removed[a,b]

Model	Variables Entered	Variables Removed	Method
1	DeltaNGF, Delta HMGB1[c]	.	Enter

a. Dependent Variable: Delta Skala Nyeri

b. Models are based only on cases for which Kelompok Sampel = Kontrol

ested variables entered.

Model Summary

Model	R Kelompok Sampel = Kontrol (Selected)	R Square	Adjusted R Square	Std. Error of the Estimate
1	.194[a]	.038	-.075	.884

a. Predictors: (Constant), DeltaNGF, Delta HMGB1

ANOVA[a,b]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	.521	2	.260	.333	.721[c]
	Residual	13.279	17	.781		
	Total	13.800	19			

a. Dependent Variable: Delta Skala Nyeri

b. Selecting only cases for which Kelompok Sampel = Kontrol

c. Predictors: (Constant), DeltaNGF, Delta HMGB1

Coefficients[a,b]

Model		Unstandardized Coefficients B	Unstandardized Coefficients Std. Error	Standardized Coefficients Beta	t	Sig.
1	(Constant)	1.020	.234		4.360	.000
	Delta HMGB1	.000	.000	.140	.587	.565
	DeltaNGF	.052	.102	.122	.512	.615

a. Dependent Variable: Delta Skala Nyeri

b. Selecting only cases for which Kelompok Sampel = Kontrol

```
REGRESSION
  /SELECT=GrupKode EQ 1
  /MISSING LISTWISE
  /STATISTICS COEFF OUTS R ANOVA
  /CRITERIA=PIN(.05) POUT(.10)
  /NOORIGIN
  /DEPENDENT DeltaODI
  /METHOD=ENTER DeltaHMGB DeltaNGF.
```

Regression

Notes

Output Created		19-OCT-2023 21:41:25
Comments		
Input	Data	C:\Users\LENOVO\Desktop\HMGB-1\HASIL\Statistik\Hasil_S3.sav
	Active Dataset	DataSet1
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	57
Missing Value Handling	Definition of Missing	User-defined missing values are treated as missing.
	Cases Used	Statistics are based on cases with no missing values for any variable used.
Syntax		REGRESSION /SELECT=GrupKode EQ 1 /MISSING LISTWISE /STATISTICS COEFF OUTS R ANOVA /CRITERIA=PIN(.05) POUT(.10) /NOORIGIN /DEPENDENT DeltaODI /METHOD=ENTER DeltaHMGB DeltaNGF.
s	Processor Time	00:00:00,00

	Elapsed Time	00:00:00,01
	Memory Required	4176 bytes
	Additional Memory Required for Residual Plots	0 bytes

Variables Entered/Removed[a,b]

Model	Variables Entered	Variables Removed	Method
1	DeltaNGF, Delta HMGB1[c]	.	Enter

a. Dependent Variable: DeltaODI

b. Models are based only on cases for which Kelompok Sampel = Intervensi

c. All requested variables entered.

Model Summary

Model	R Kelompok Sampel = Intervensi (Selected)	R Square	Adjusted R Square	Std. Error of the Estimate
1	.429[a]	.184	.136	1.783

a. Predictors: (Constant), DeltaNGF, Delta HMGB1

ANOVA[a,b]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	24.338	2	12.169	3.828	.032[c]
	Residual	108.094	34	3.179		
	otal	132.432	36			

nt Variable: DeltaODI

only cases for which Kelompok Sampel = Intervensi

c. Predictors: (Constant), DeltaNGF, Delta HMGB1

Coefficients[a,b]

Model		Unstandardized Coefficients		Standardized Coefficients		
		B	Std. Error	Beta	t	Sig.
1	(Constant)	9.993	.377		26.496	.000
	Delta HMGB1	.000	.000	-.144	-.916	.366
	DeltaNGF	.240	.098	.383	2.440	.020

a. Dependent Variable: DeltaODI

b. Selecting only cases for which Kelompok Sampel = Intervensi

```
REGRESSION
  /SELECT=GrupKode EQ 2
  /MISSING LISTWISE
  /STATISTICS COEFF OUTS R ANOVA
  /CRITERIA=PIN(.05) POUT(.10)
  /NOORIGIN
  /DEPENDENT DeltaODI
  /METHOD=ENTER DeltaHMGB DeltaNGF
  /RESIDUALS NORMPROB(ZRESID).
```

Regression

Notes

Output Created		19-OCT-2023 22:04:28
Comments		
Input	Data	C:\Users\LENOVO\Desktop\HMGB-1\HASIL\Statistik\Hasil_S3.sav
	Active Dataset	DataSet1
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	57
Missing Value Handling	Definition of Missing	User-defined missing values are treated as missing.
	Cases Used	Statistics are based on cases with no missing values for any variable used.

Syntax		REGRESSION /SELECT=GrupKode EQ 2 /MISSING LISTWISE /STATISTICS COEFF OUTS R ANOVA /CRITERIA=PIN(.05) POUT(.10) /NOORIGIN /DEPENDENT DeltaODI /METHOD=ENTER DeltaHMGB DeltaNGF /RESIDUALS NORMPROB(ZRESID).
Resources	Processor Time	00:00:01,30
	Elapsed Time	00:00:02,23
	Memory Required	4192 bytes
	Additional Memory Required for Residual Plots	280 bytes

Variables Entered/Removed[a,b]

Model	Variables Entered	Variables Removed	Method
1	DeltaNGF, Delta HMGB1[c]	.	Enter

a. Dependent Variable: DeltaODI

b. Models are based only on cases for which Kelompok Sampel = Kontrol

c. All requested variables entered.

Model Summary[b,c]

Model	R Kelompok Sampel = Kontrol (Selected)	R Kelompok Sampel ~= Kontrol (Unselected)	R Square	Adjusted R Square	Std. Error of the Estimate
	.170[a]	.	.029	-.085	2.084

ors: (Constant), DeltaNGF, Delta HMGB1

noted otherwise, statistics are based only on cases for which Kelompok Sampel = Kontrol.

c. Dependent Variable: DeltaODI

ANOVA[a,b]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	2.199	2	1.100	.253	.779[c]
	Residual	73.801	17	4.341		
	Total	76.000	19			

a. Dependent Variable: DeltaODI

b. Selecting only cases for which Kelompok Sampel = Kontrol

c. Predictors: (Constant), DeltaNGF, Delta HMGB1

Coefficients[a,b]

Model		Unstandardized Coefficients		Standardized Coefficients		
		B	Std. Error	Beta	t	Sig.
1	(Constant)	5.796	.551		10.513	.000
	Delta HMGB1	.000	.001	.161	.672	.511
	DeltaNGF	.041	.241	.041	.172	.865

a. Dependent Variable: DeltaODI

b. Selecting only cases for which Kelompok Sampel = Kontrol

LAMPIRAN 3 Angket Oswestry Disability Index

Angket "Modified Oswestry Low Back Pain Disability Questionnaire"

Nama:

Umur:

Tgl Pemeriksaan

Berikan tanda √ pada salah satu pilihan jawaban yang paling menggambarkan keadaan anda.

1. Intensitas nyeri
o Saat ini saya tidak nyeri (Nilai : 0)
o Saat ini nyeri terasa sangat ringan (Nilai : 1)
o Saat ini nyeri terasa ringan (Nilai : 2)
o Saat ini nyeri terasa agak berat (Nilai : 3)
o Saat ini nyeri terasa sangat berat (Nilai : 4)
o Saat ini nyeri terasa amat sangat berat (Nilai : 5)

2. Perawatan diri (mandi, berpakaian dll)
o Saya merawat diri secara normal tanpa disertai timbulnya nyeri (Nilai : 0)
o Saya merawat diri secara normal tetapi terasa sangat nyeri (Nilai : 1)
o Saya merawat diri secara hati-hati dan lamban karena terasa sangat nyeri (Nilai : 2)
o Saya memerlukan sedikit bantuan saat merawat diri (Nilai : 3)
o Setiap hari saya memerlukan bantuan saat merawat diri (Nilai : 4)
o Saya tidak bisa berpakaian dan mandi sendiri, hanya tiduran di bed (Nilai : 5)

3. Aktifitas Mengangkat
o Saya dapat mengangkat benda berat tanpa disertai timbulnya nyeri (Nilai : 0)
o Saya dapat mengangkat benda berat tetapi disertai timbulnya nyeri (Nilai : 1)
o Nyeri membuat saya tidak mampu mengangkat benda berat dari lantai, tetapi saya mampu mengangkat benda berat yang posisinya mudah, misalnya di atas meja. (Nilai : 2)
o Nyeri membuat saya tidak mampu mengangkat benda berat dari lantai, [illegible]aya mampu mengangkat benda ringan dan sedang yang posisinya [illegible]misalnya di atas meja. (Nilai : 3)
[illegible]anya dapat mengangkat benda yang sangat ringan (Nilai : 4)

o Saya tidak dapat mengangkat maupun membawa benda apapun (Nilai : 5)

4. Berjalan
o Saya mampu berjalan berapapun jaraknya tanpa disertai timbulnya nyeri (Nilai : 0)
o Saya hanya mampu berjalan tidak lebih dari 1 mil karena nyeri (Nilai : 1)
o Saya hanya mampu berjalan tidak lebih dari 1/4 mil karena nyeri (Nilai : 2)
o Saya hanya mampu berjalan tidak lebih dari 100 yard karena nyeri (Nilai : 3)
o Saya hanya mampu berjalan menggunakan alat bantu tongkat atau kruk (Nilai : 4)
o Saya hanya mampu tiduran, untuk ke toilet dengan merangkak (Nilai : 5)

5. Duduk o Saya mampu duduk pada semua jenis kursi selama aku mau (Nilai : 0)
o Saya mampu duduk pada kursi tertentu selama aku mau (Nilai : 1)
o Saya hanya mampu duduk pada kursi tidak lebih dari 1 jam karena nyeri (Nilai : 2)
o Saya hanya mampu duduk pada kursi tidak lebih dari 1/2 jam karena nyeri (Nilai : 3)
o Saya hanya mampu duduk pada kursi tidak lebih dari 10 menit karena nyeri (Nilai : 4)
o Saya tidak mampu duduk karena nyeri (Nilai : 5)

6. Berdiri
o Saya mampu berdiri selama aku mau (Nilai : 0)
o Saya mampu berdiri selama aku mau tetapi timbul nyeri (Nilai : 1)
o Saya hanya mampu berdiri tidak lebih dari 1 jam karena nyeri (Nilai : 2)
o Saya hanya mampu berdiri tidak lebih dari 1/2 jam karena nyeri (Nilai : 3)
o Saya hanya mampu berdiri tidak lebih dari 10 menit karena nyeri (Nilai : 4)
o Saya tidak mampu berdiri karena nyeri (Nilai : 5)

7. Tidur
o Tidurku tak pernah terganggu oleh timbulnya nyeri (Nilai : 0)
o Tidurku terkadang terganggu oleh timbulnya nyeri (Nilai : 1)
o Karena nyeri tidurku tidak lebih dari 6 jam (Nilai : 2)
o Karena nyeri tidurku tidak lebih dari 4 jam (Nilai : 3)
o Karena nyeri tidurku tidak lebih dari 2 jam (Nilai : 4)
o Saya tidak bisa tidur karena nyeri (Nilai : 5)

as Seksual (bila memungkinkan)
.s seksualku berjalan normal tanpa disertai timbulnya nyeri (Nilai : 0)

o Aktifitas seksualku berjalan normal tetapi disertai timbulnya nyeri (Nilai : 1)
o Aktifitas seksualku berjalan hampir normal tetapi sangat nyeri (Nilai : 2)
o Aktifitas seksualku sangat terhambat oleh adanya nyeri (Nilai : 3)
o Aktifitas seksualku hampir tak pernah karena adanya nyeri (Nilai : 4)
o Aktifitas seksualku tidak pernah bisa terlaksana karena nyeri (Nilai : 5)

9. Kehidupan Sosial
o Kehidupan sosialku berlangsung normal tanpa gangguan nyeri (Nilai : 0)
o Kehidupan sosialku berlangsung normal tetapi ada peningkatan derajat nyeri (Nilai : 1) 50
o Kehidupan sosialku yang aku sukai misalnya olahraga tidak begitu terganggu adanya nyeri (Nilai : 2) o Nyeri menghambat kehidupan sosialku sehingga aku jarang keluar rumah (Nilai : 3)
o Nyeri membuat kehidupan sosialku hanya berlangsung di rumah saja (Nilai : 4)
o Saya tidak mempunyai kehidupan sosial karena nyeri (Nilai : 5)

10. Bepergian / Melakukan Perjalanan
o Saya bisa melakukan perjalanan ke semua tempat tanpa adanya nyeri (Nilai : 0)
o Saya bisa melakukan perjalanan ke semua tempat tetapi timbul nyeri (Nilai : 1)
o Nyeri memang mengganggu tetapi saya bisa melakukan perjalanan lebih dari 2 jam (Nilai : 2)
o Nyeri menghambatku sehingga saya hanya bisa melakukan perjalanan kurang dari 1 jam (Nilai : 3)
o Nyeri menghambatku sehingga saya hanya bisa melakukan perjalanan pendek kurang dari 30 menit (Nilai : 4)
o Nyeri menghambatku untuk melakukan perjalanan kecuali hanya berobat (Nilai : 5)

Interpretasi

Hasil Dari 10 pertanyaan, jumlahkan seluruh nilai yang didapat, lalu dihitung dengan rumus :

0% - 20 % ◊ Minimal disability : Pasien dapat melakukan aktivitas sehari-hari tanpa terganggu oleh rasa nyeri.
51 21% - 40% ◊ Moderate disability : Pasien merasakan nyeri yang lebih dan mulai kesulitan dalam melakukan aktivitas sehari-hari seperti duduk, gkat barang dan berdiri.
0% ◊ Severe disability : Nyeri terasa sepanjang waktu dan aktivitas ari mulai terganggu karena rasa nyeri.

61% - 80% ◊ Crippled : Nyeri yang timbul mengganggu seluruh aktivitas seharihari. 81% - 100% ◊ Pasien sudah sangat tersiksa oleh nyeri yang timbul