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LAMPIRAN

Lampiran 1.

Ijin Persetujuan Etik



REKOMENDASI PERSETUJUAN ETIK

Nomor : 85/UN4.6.4.5.31/ PP36/ 2022

Tanggal: 18 Februari 2022

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

No Protokol	UH22010024	No Sponsor Protokol	
Peneliti Utama	dr. Stephanie Tanjung	Sponsor	
Judul Peneliti	HUBUNGAN DERAJAT PROPTOSIS TERHADAP DIMENSI BOLA MATA PADA PASIEN GRAVES OPHTHALMOPATHY DI RSUP WAHIDIN SUDIROHUSODO MAKASSAR		
No Versi Protokol	2	Tanggal Versi	9 Februari 2022
No Versi PSP	2	Tanggal Versi	9 Februari 2022
Tempat Penelitian	RS Dr. Wahidin Sudirohusodo Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal	Masa Berlaku 18 Februari 2022 sampai 18 Februari 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. Agusssalim Bukhari, 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 Lapoe 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.

Ringkasan Penelusuran Jurnal

No.	Nama Peneliti	Kesimpulan
1.	Yildirim, et al. 2020	Tidak terdapat perbedaan signifikan antara <i>axial length</i> pada keadaan CAS aktif dan inaktif. Tetapi faktor yang mempengaruhi <i>axial length</i> adalah ketebalan koroid dimana tidak dipengaruhi dengan nilai CAS berdasarkan analisis regresi ($p=0,737$).
2.	Zhou et al, 2021	tidak terdapat perbedaan signifikan antara <i>axial length</i> dengan pasien GO aktif dan inaktif berdasarkan CAS
3.	W. O. Chan et al, 2009	bahwa <i>axial length</i> memiliki korelasi terhadap protrusi okular dimana setiap 4 mm <i>axial length</i> meningkat 1 mm dalam pengukuran <i>exophthalmometric</i>
4.	Kanar, 2021	meneliti terhadap dua variabel yang berbeda yaitu GO aktif dan GO tidak aktif dalam penelitiannya <i>axial length</i> memiliki hubungan statistic yang bermakna dan tidak ada perbedaan <i>axial length</i> antara GO yang aktif dan tidak aktif.
5.	Zhou et al, 2021	ditemukan hasil yang tidak signifikan antara <i>anterior chamber depth</i> dengan pada CAS aktif dan inaktif.

6.	El-ghazawy et al, 2019	tidak ada hubungan yang signifikan antara <i>axial length</i> dan ACD apabila <i>axial length</i> dalam keadaan normal.
7.	Akmaz et al, 2021	<i>anterior chamber depth</i> memiliki korelasi negative yang bermakna
8.	Mongkolareepong et al. 2022	proptosis pada kelopak mata dapat menghasilkan tekanan kedalam superior kornea yang menyebabkan perubahan kelengkungan pada kornea
9.	Chen et al, 2011	terdapat korelasi yang sangat kuat antara derajat proptosis dengan kurvatura kornea.
10.	Mombaerts et al, 2006	perubahan astigmatisme kornea dapat disebabkan oleh fibrosis jaringan lunak di superolateral orbita bukan karena dipengaruhi operasi orbital, strabismus maupun kelopak mata.

Lampiran 3.

FORMULIR PERSETUJUAN

Saya yang bertanda tangan di bawah ini :

Nama :

Umur : tahun

Alamat :

Telepon/HP :

Menyatakan bersedia untuk berpartisipasi pada penelitian ini yang berjudul :

“Hubungan Derajat Proptosis Terhadap Dimensi Bola Mata Pada Pasien Graves Ophthalmopathy Di RSUP Wahidin Sudirohusodo Makassar “

setelah mendengar/membaca dan mengerti penjelasan yang diberikan mengenai tujuan dan manfaat yang akan didapatkan pada penelitian ini, khususnya bagi kemajuan ilmu kedokteran.

Nama

Tanda tangan

Tgl/Bln/Thn

Responden
.....

Saksi
.....

Penanggung jawab penelitian :

dr. Stephanie Tanjung
Perumahan Lily blok H no 24
Telp. 0852 5678 2184

Penanggung jawab medik :

dr. Muhammad Abrar Ismail, Sp.M(K), M.Kes
Jl. .Sultan Alaudin No. 84 A
Telp. 0813 4388 4693

DISETUJUI OLEH KOMISI PENELITIAN
KESEHATAN FAKULTAS KEDOKTERAN
UNHAS

TGL.....2021

Lampiran 4.

LEMBAR OBSERVASI

I. KARAKTERISTIK RESPONDEN	
Nama	
Umur	() Tahun
Jenis Kelamin	() Laki-Laki () Perempuan
Gejala Klinis	() Proptosis () Retraksi Kelopak Mata () Diplopia () Nyeri () Penglihatan menurun
Onset	() bulan/tahun
Riwayat <i>Graves Disease</i>	() bulan/tahun
Riwayat Perokok	() Aktif/Pasif
<i>Soft Tissue Involvement</i>	() Edema palpebral () Eritema palpebra () Injeksi konjungtiva () Kemosis konjungtiva () Inflamasi karunkula/plika () Corneal Involvement
Proptosis	Intercantal Distance = _____ mm OD = _____ mm OS = _____ mm Derajat proptosis NOSPECS - 0 dimana tidak ada proptosis, - a adalah 3 – 4 mm, - b adalah 5 – 7 mm, dan - c adalah > 8 mm.
Fissura Interpalpebralis	OD = _____ mm OS = _____ mm
Retraksi palpebral	OD = _____ mm OS = _____ mm
Levator Function	OD = _____ mm OS = _____ mm
Lagofthalmus	OD = _____ mm OS = _____ mm
Bell's phenomenon	Ada/tidak ada

Integritas Kornea	() Normal () Punctate keratopathy () Ulcer () Perforation
Visus (Snellen)	
RAPD	/
Ishihara test	
Funduskopi (Optic disc)	normal/atrophy/edema
Axial Length	OD () OS ()
Anterior Chamber Depth	OD () OS ()
Kurvatura Kornea	OD () OS ()

II. VARIABEL PENELITIAN

A. *CLINICAL ACTIVITY SCORE*

Klasifikasi Oftalmopati Graves berdasarkan *Clinical Activity Score* :

Pada kunjungan awal CAS, poin 1-7

1. Nyeri orbita spontan
2. Nyeri bila menggerakkan bola mata
3. Edema palpebral yang diduga akibat Oftalmopati Graves aktif
4. Eritema palpebral yang diduga akibat Oftalmopati Graves aktif
5. Injeksi konjungtiva yang diduga akibat Oftalmopati Graves aktif
6. Kemosis konjungtiva
7. Inflamasi Karunkula atau plika

Pasien yang dinilai setelah di follow up (1 – 3 bulan) sampai 10 poin (8-10)

8. Peningkatan >2mm proptosis
9. Penurunan gerak bola mata pada salah satu arah > 8 derajat
10. Penurunan visus ekuivalen ke-1 baris *Snellen*

() Fase aktif; skor lebih dari 3 dari 7 poin pertama ($\geq 3/7$), atau lebih dari 4 poin dari total 10 poin ($\geq 4/10$) pada pemeriksaan berikutnya secara berturut-turut.

() Fase tenang; skor kurang dari 3 dari 7 poin pertama ($< 3/7$), atau kurang dari 4 poin dari total 10 poin ($< 4/10$) pada pemeriksaan berikutnya secara berturut-turut.

B. Derajat Proptosis Kriteria *NOSPECS Modified*

- 0 dimana tidak ada proptosis,
- a adalah 3 – 4 mm,
- b adalah 5 – 7 mm, dan
- c adalah > 8 mm.

Lampiran 5.

Master data

No	Tgl Sampel	ID Sampel	Nama	Jenis Kelamin	RM	Tgl lahir	RS	Thyroid	Onset TED (tahun)	Onset Graves' Disease	TRAb pertama	R4	TSH	Pulse Steroid	Visus OD	Visus OS
1	2/7/2022	A	Asriadi	L	893780	8/1/1983	RSWS	Hyperthyroid	2	2	3.55	1.66	0.05	4	1/300	20/40
2	3/16/2022	B	Stefanus	L	965457	7/1/1987	RSWS	Hyperthyroid	4	6		3.33	0.09	0	20/60	20/120
3	3/31/2022	C	Arum Dwi	P	954283	12/10/1996	RSWS	Hyperthyroid	1	1	7.31	2.16	0.05	0	20/20	20/20
4	4/4/2022	D	Haerun	L	932390	7/2/1990	RSWS	Hyperthyroid	1	1		1.27	0.05	12	20/20	20/20
5	4/6/2022	E	Hedi Pramadan	L	973737	12/21/1997	RSWS	Hyperthyroid	2	2		0.64	0.07	0	20/50	20/50
6	3/14/2022	F	Nelvi Mustika Indah	P	886246	10/21/2005	RSWS	Hyperthyroid	1	2	16.61	0.9	1.48	1	KM 20/20	KM 20/20
7	4/14/2022	G	Basir	L	179553	19/11/1987	RSUH	Hyperthyroid	2	17					20/60	1/300
8	3/4/2022	H	Nelly Karyawati	P	969331	12/27/1986	RSWS	Hyperthyroid	1	1.3	6.09	0.77	0.65	0	20/30	20/20
9	2/14/2022	I	Ernawati	P	890423	8/12/1989	RSWS	Euthyroid	3	8	0.9	1.47	3.81	3	20/20	20/20

TIO		Gejala Klinis										Soft Tissue Involvement / CAS					CAS SCORE	Interpretasi CAS
OD	OS	Proptosis	Kelopak	Diplopi	Nyeri	Inglikatan Menun	Orbita	Gerakan	Palpebra	Palpebra	Konjungtiva	Konjungtiva	Karunkula	>2mm	gerakan	Visus 1		
19	15 v	v	x	x	v		0	0	1	0	0	0	1	1	1	1	1	5 Active
8	19 v	v	x	x	v		0	0	1	0	1	0	1	0	0	0	0	3 Active
14	12 v	X	X	X	X		0	0	1	0	0	0	0	0	0	0	0	1 Inactive
16	17 v	V	X	X	X		0	0	0	0	0	0	1	1	1	1	0	3 Inactive
15	16 v	X	X	X	X		0	0	1	0	0	0	1	0	0	0	0	2 Inactive
18	19 v	X	X	X	X		0	0	1	0	0	0	1	0	0	0	0	2 Inactive
16	28 v	V	X	V	V		1	1	1	0	1	1	1	0	0	0	0	6 Active
16	16 v	X	X	X	X		0	0	1	0	0	0	1	0	0	0	0	2 Inactive
14	15 v	v	x	x	x		0	0	1	1	1	0	1	0	0	0	0	4 Active

Distance	HERTEL BAR		AJAT PROPTOSIS		Intrapalpebralis		Intrapalpebralis			Integritas Kornea	RAPD	Riwayat Merokok	EUGOGO
	OD	OS	OD	OS	FIP	(Superior)	(Inferior)	FIP	(Superior)				
115	29	25 C	B		16	7	9	14	7	7 Jernih	-/-	Ada	Sight Treating
110	20	18 A			16	10	6	13	7	6 s (+)	-/-	Ada	Sight Treating
114	18	18	O	O	12	5	7	11	6	5 Jernih	-/-	Tidak	Mild TED
109	20	20 A	A		15	8	7	16	8	8 Jernih	-/-	Ada	Moderate TED
115	22	25 A	B		14	6	8	15	7	8 Jernih	-/-	Ya	Moderate TED
111	21	20 A	A		13	5	8	12	5	7 Jernih	-/-	Pasif	Mild TED
120	28	30 C	C		14	8	6	17	10	7 us	Sdn	Ya	Sight Treating
111	18	20	O A		11	4	7	11	5	6 Jernih	-/-	Tidak	Mild TED
115	25	25 C	C		13	5	8	13	4	9 Jernih	-/-	Pasif	Mild TED

AXIAL LENGTH		ACD		CC			
OD	OS	OD	OS	OD (Flat)	OD (steep)	OS (Flat)	OS (Steep)
23.9	23.64	2.86	3.23	42.03	43.05	42.51	43.6
24.81	24.71	3.5	3.26	41.58	42.07	41.36	42.86
22.69	22.7	3.38	3.26	43.51	44.43	43.46	44.7
24.17	24.33	2.92	2.97	40.4	40.85	40.11	40.85
24.49	24.39	3.47	3.44	45.04	46.3	44.99	46.33
25	25.28	3.57	3.62	41.51	43.32	41.72	43.12
25.28		2.82		39.61	41.48		
23.63	23.75	3.15	3.2	42.67	44.2	42.54	43.58
24.38	24.39	3.21	3.26	45.13	46.41	44.7	46.21

LAMPIRAN 6.
Hasil Uji Statistik

Jenis Kelamin

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Laki-laki	5	55.6	55.6	55.6
	Perempuan	4	44.4	44.4	100.0
	Total	9	100.0	100.0	

Thyroid

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Hyperthyroid	8	88.9	88.9	88.9
	Euthyroid	1	11.1	11.1	100.0
	Total	9	100.0	100.0	

CAS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Active	4	44.4	44.4	44.4
	Inactive	5	55.6	55.6	100.0
	Total	9	100.0	100.0	

Riwayat Rokok

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Ada	5	55.6	55.6	55.6
	Tidak Ada	2	22.2	22.2	77.8
	Pasif	2	22.2	22.2	100.0
	Total	9	100.0	100.0	

EUGOOGO

		Frequency	Percent	Valid Percent	Cumulative Percent
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Valid	Sight Threatening	3	33.3	33.3	33.3
	Mild TED	4	44.4	44.4	77.8
	Moderate TED	2	22.2	22.2	100.0
	Total	9	100.0	100.0	

Descriptives

		Statistic	Std. Error
Usia	Mean	29.63	2.367
	95% Confidence Interval for Mean	Lower Bound	24.03
		Upper Bound	35.22
	5% Trimmed Mean	29.81	
	Median	31.50	
	Variance	44.839	
	Std. Deviation	6.696	
	Minimum	18	
	Maximum	38	
	Range	20	
	Interquartile Range	11	
	Skewness	-.638	.752
	Kurtosis	-.487	1.481

Descriptives

		Statistic	Std. Error
Onset TED (bulan)	Mean	22.67	4.216
	95% Confidence Interval for Mean	Lower Bound	12.94
		Upper Bound	32.39
	5% Trimmed Mean	21.85	
	Median	24.00	
	Variance	160.000	
	Std. Deviation	12.649	
	Minimum	12	
	Maximum	48	
	Range	36	
	Interquartile Range	18	
	Skewness	1.094	.717
	Kurtosis	.611	1.400

Onset Greaves (bulan)	Mean		53.67	21.192
	95% Confidence Interval for Mean	Lower Bound	4.80	
		Upper Bound	102.54	
	5% Trimmed Mean		47.63	
	Median		24.00	
	Variance		4042.000	
	Std. Deviation		63.577	
	Minimum		12	
	Maximum		204	
	Range		192	
	Interquartile Range		71	
	Skewness		2.001	.717
	Kurtosis		4.031	1.400

AL * Proptosis Crosstabulation

		Proptosis				Total	
		Tidak Ada Proptosis	a	b	c		
AL	Normal	Count	4	6	2	3	15
		% within Proptosis	100.0%	85.7%	100.0%	75.0%	88.2%
	Panjang	Count	0	1	0	1	2
		% within Proptosis	0.0%	14.3%	0.0%	25.0%	11.8%
Total		Count	4	7	2	4	17
		% within Proptosis	100.0%	100.0%	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	1.518 ^a	3	.678
Likelihood Ratio	2.075	3	.557
Linear-by-Linear Association	.764	1	.382
N of Valid Cases	17		

a. 7 cells (87.5%) have expected count less than 5. The minimum expected count is .24.

Descriptives

		Proptosis		Statistic	Std. Error		
Flat	Tidak Ada Proptosis	Mean		42.7500	.50168		
		95% Confidence Interval for		Lower Bound	41.1534		
		Mean	Upper Bound	44.3466			
		5% Trimmed Mean		42.7850			
		Median		43.0650			
		Variance		1.007			
		Std. Deviation		1.00336			
		Minimum		41.36			
		Maximum		43.51			
		Range		2.15			
		Interquartile Range		1.81			
		Skewness		-1.247	1.014		
		Kurtosis		.711	2.619		
		a		Mean		41.8429	.61697
				95% Confidence Interval for		Lower Bound	40.3332
Mean	Upper Bound			43.3525			
5% Trimmed Mean				41.7615			
Median				41.5800			
Variance				2.665			
Std. Deviation				1.63235			
Minimum				40.11			
Maximum				45.04			
Range				4.93			
Interquartile Range				2.14			
Skewness				1.328	.794		
Kurtosis				2.362	1.587		
b				Mean		43.7500	1.24000
				95% Confidence Interval for		Lower Bound	27.9943
		Mean	Upper Bound	59.5057			
		5% Trimmed Mean		.			
		Median		43.7500			

		Variance	3.075	
		Std. Deviation	1.75362	
		Minimum	42.51	
		Maximum	44.99	
		Range	2.48	
		Interquartile Range	.	
		Skewness	.	.
		Kurtosis	.	.
	c	Mean	42.8675	1.28419
		95% Confidence Interval for Lower Bound	38.7806	
		Mean Upper Bound	46.9544	
		5% Trimmed Mean	42.9228	
		Median	43.3650	
		Variance	6.597	
		Std. Deviation	2.56838	
		Minimum	39.61	
		Maximum	45.13	
		Range	5.52	
		Interquartile Range	4.81	
		Skewness	-.685	1.014
		Kurtosis	-1.966	2.619
Step	Tidak Ada Proptosis	Mean	44.0475	.40881
		95% Confidence Interval for Lower Bound	42.7465	
		Mean Upper Bound	45.3485	
		5% Trimmed Mean	44.0772	
		Median	44.3150	
		Variance	.668	
		Std. Deviation	.81761	
		Minimum	42.86	
		Maximum	44.70	
		Range	1.84	
		Interquartile Range	1.44	
		Skewness	-1.631	1.014
		Kurtosis	2.849	2.619
	a	Mean	42.8700	.71272
		95% Confidence Interval for Lower Bound	41.1260	
		Mean Upper Bound	44.6140	

	5% Trimmed Mean	42.7917	
	Median	43.1200	
	Variance	3.556	
	Std. Deviation	1.88568	
	Minimum	40.85	
	Maximum	46.30	
	Range	5.45	
	Interquartile Range	2.73	
	Skewness	.829	.794
	Kurtosis	.964	1.587
b	Mean	44.9650	1.36500
	95% Confidence Interval for Lower Bound	27.6210	
	Mean	Upper Bound	62.3090
	5% Trimmed Mean	.	
	Median	44.9650	
	Variance	3.726	
	Std. Deviation	1.93040	
	Minimum	43.60	
	Maximum	46.33	
	Range	2.73	
	Interquartile Range	.	
	Skewness	.	.
	Kurtosis	.	.
c	Mean	44.2875	1.21156
	95% Confidence Interval for Lower Bound	40.4318	
	Mean	Upper Bound	48.1432
	5% Trimmed Mean	44.3256	
	Median	44.6300	
	Variance	5.871	
	Std. Deviation	2.42312	
	Minimum	41.48	
	Maximum	46.41	
	Range	4.93	
	Interquartile Range	4.49	
	Skewness	-.345	1.014
	Kurtosis	-3.983	2.619

Correlations

		Proptosis	Flat	Step
Proptosis	Pearson Correlation	1	.138	.172
	Sig. (2-tailed)		.596	.508
	N	18	17	17
Flat	Pearson Correlation	.138	1	.976**
	Sig. (2-tailed)	.596		.000
	N	17	17	17
Step	Pearson Correlation	.172	.976**	1
	Sig. (2-tailed)	.508	.000	
	N	17	17	17

** . Correlation is significant at the 0.01 level (2-tailed).