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KEMENTERIAN RISET, TEKNOLOGI DAN PENDIDIKAN TINGGI



KOMITE ETIK PENELITIAN KESEHATAN

Fakultas Kedokteran Universitas Hasanuddin

RSPTN Universitas Hasanuddin

RSUP dr. Wahidin Sudirohusodo Makassar

Sekretariat : Lantai 2 Gedung Laboratorium Terpadu FKUH

JL. PERINTIS KEMERDEKAAN KAMPUS TAMALANREA KM.10, MAKASSAR 90245

Contact Person: dr. Agussalim Bukhari, M.Med, Ph.D, Sp.GK 081241850858

e-mail:agussalimbukhari@yahoo.com

Lampiran 1.

FORMULIR PERSETUJUAN

Saya yang bertanda tangan di bawah ini :

Nama : Umur : tahun

Alamat :

Telepon/HP :

Menyatakan bersedia untuk berpartisipasi pada penelitian ini yang berjudul :

“ Pengaruh Diameter Kapsulotomi Posterior Laser Nd: YAG Terhadap Perubahan Kedalaman Bilik Mata Depan, Sudut Iridokornea, Dan Luaran Tajam Penglihatan Pada Pasien Opasifikasi Kapsul Posterior “

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. Widodo Prima Utama
Perumahan Diyandara Residence,
blok A5, Wessabbe, Tamalanrea, Makassar.
Telp. 082393277703

DISETUJUI OLEH KOMISI PENELITIAN
KESEHATAN FAKULTAS KEDOKTERAN
UNHASTGL.....2022

Penanggung jawab medis :
dr. Muhammad Abrar Ismail, Sp.M(K), M. Kes
Jl. Sultan Alaudin No. 84 A
Telp. 081343884693

Lampiran 2. Lembar Observasi

LEMBAR OBSERVASI

I.KARAKTERISTIK RESPONDEN	
Nama	
No. RM	
No Telp	
Alamat	
Umur	() Tahun (> 40 tahun)
Jenis Kelamin	() Laki-Laki () Perempuan
Gejala Klinis	() Penglihatan menurun/kabur () Diplopia () Nyeri () Lainnya, sebutkan
Lama menderita PCO	() bulan/tahun
Riwayat operasi katarak	() bulan/tahun () Fakoemulsifikasi/lainnya () Ada/tidak komplikasi operasi () Pseudofakia/Afakia
Riwayat penyakit mata lainnya	() Glaukoma () Retinopati Diabetik () Miopia/Hiperopia () Lainnya, sebutkan
Riwayat penyakit sistemik	() DM lebih dari 5 tahun () Hipertensi () Stroke () Alergi () Lainnya, Sebutkan
Riwayat trauma	()
Riwayat operasi mata (selain operasi katarak)	
Riwayat Pemakaian Obat	() ()
Riwayat kacamata	()
Keterangan lainnya	

PEMERIKSAAN PRA LASER	
Hari/tanggal:	
Tajam Penglihatan	VOD: VOS:
TIO	TIOD: mmHg TIOS: mmHg
Segmen Anterior	() sebutkan jika ada kelainan
OCT Anterior	BMD: ... mm ACA: T... N... mm
Pemeriksaan Post Laser	
Hari/tanggal:	
Diameter Kapsulotomi Posterior (diukur dengan <i>slit lamp</i>)	Horizontal x Vertikal (x) mm
PEMERIKSAAN POST LASER (HARI KE-1)	
Hari/tanggal:	
Tajam Penglihatan	VOD: VOS:
TIO	TIOD: mmHg TIOS: mmHg
Segmen Anterior	() sebutkan jika ada kelainan
OCT Anterior	BMD: ... mm ACA: T... N... mm

PEMERIKSAAN POST LASER (HARI KE-7)

Hari/tanggal:

Tajam Penglihatan

VOD:

VOS:

VOD (BCVA):

VOS (BCVA):

TIO

TIOD: mmHg

TIOS: mmHg

Segmen Anterior

()

sebutkan jika ada kelainan

.....

OCT Anterior

BMD: ... mm

ACA: T... N... mm

Keterangan lainnya:

Lampiran 3. Data Dasar Penelitian

No.	Nama	Usia (tahun)	Jenis Kelamin	Mata OD/S	Op Phaco (bulan)	Menderita PCO (bulan)	Penyakit Sistemik	VA-Pre (logMar)	TIO-Pre (mmHg)	ACD-Pre (mm)	ACA Temporal Pre (degree)	ACA Nasal Pre (degree)	ACA_Average_Pre	Diameter H (mm)	Diameter V (mm)	KELOMPOK
1	Sukxxx	70	L	OD	10	3	Tidak ada	0,8	11	3,33	32	32	32	4,2	4,1	2
2	Siti Naxxx	63	P	OD	12	4	Hipertensi	0,4	10	2,69	31	26	28,5	5,6	5,8	2
3	Bixxx	76	P	OS	48	12	Hipertensi	0,7	14	2,84	30	29	29,5	4,6	4,8	2
4	Mahjuxxxx	46	L	OD	4	1	Tidak ada	0,7	16	3,05	27	27	27	4,1	4	2
5	Naxxx	52	L	OS	24	6	Tidak ada	0,6	19	2,96	33	32	32,5	4,2	4,1	2
6	Naxxx	52	L	OD	10	3	Tidak ada	0,6	18	2,9	31	29	30	4,3	4,2	2
7	Muhaxxxx	70	P	OS	36	3	Tidak ada	0,4	10	3,41	34	26	30	4,1	4,1	2
8	Laxxx	69	L	OD	12	4	Tidak ada	1,47	12	3,24	40	36	38	4	4,1	2
9	Isabxxx	62	P	OS	10	2	Tidak ada	1	22	2,99	26	33	29,5	4	4,1	2
10	Marbxxx	67	P	OD	48	12	Tidak ada	0,7	11	3,31	33	32	32,5	3,2	3,2	1
11	Marbxxx	67	P	OS	36	8	Tidak ada	0,6	15	3,1	37	24	30,5	4,1	4	2
12	Nurfbxxx	71	P	OD	11	3	Hipertensi	0,6	16	3,08	32	30	31	4,2	4,3	2
13	Nurfbxxx	71	P	OS	12	3	Hipertensi	0,7	18	2,98	37	30	33,5	4	4,1	2
14	Saonxxx	77	P	OS	16	3	Hipertensi	0,5	16	3,04	41	35	38	3,3	3,2	1
15	Saonxxx	77	P	OD	18	3	Hipertensi	0,4	14	3,17	36	36	36	2,6	2,6	1
16	Noxxx	74	P	OD	5	1	Tidak ada	0,7	11	3,78	42	30	36	4,1	4,2	2
17	Arxx	46	L	OS	12	2	Tidak ada	1	16	3,52	40	31	35,5	4,2	3,1	1
18	Fatibxxx	68	P	OS	36	4	Diabetes Mellitus	0,6	16	3,42	34	33	33,5	4,1	4,2	2
19	Rahbxxx	65	L	OD	48	2	Tidak ada	0,6	13	3,35	37	33	35	3,7	3,6	1
20	Abdxxx	57	P	OD	24	2	Tidak ada	1	18	3,87	40	31	35,5	4,4	4,5	2
21	Siti Amxxx	70	P	OS	4	1	Diabetes Mellitus	0,7	17	3,36	33	38	35,5	3,2	3,2	1
22	St Asxxx	61	P	OS	6	2	Tidak ada	0,4	12	3,45	40	40	40	4,1	4	2
23	Normxxxx	64	P	OS	24	3	Tidak ada	1,3	13	3,1	30	30	30	3,1	3,2	1
24	Ferdxxxx	50	L	OD	10	2	Tidak ada	0,7	14	3,63	35	30	32,5	3,6	3,8	1
25	Ferdxxxx	50	L	OS	8	2	Tidak ada	0,6	14	3,58	31	29	30	3,5	3,4	1
26	Musdxxxxxx	76	P	OD	48	6	Tidak ada	1,3	15	3,18	29	27	28	2,6	2,5	1
27	Hasxxx	67	P	OS	24	4	Hipertensi	0,7	15	3,24	31	29	30	3,1	3	1
28	Mi Trxx	54	L	OD	12	2	Tidak ada	1,3	16	3,22	30	27	28,5	5	5,1	2
29	Basxxx	57	P	OS	36	4	Diabetes Mellitus	1	20	3,15	32	25	28,5	4,2	4,3	2
30	Yohbxxx	83	P	OS	24	6	Tidak ada	0,4	16	3,26	42	36	39	4,8	5	2
31	Jabaxxx	65	P	OS	12	2	Tidak ada	0,6	14	3,45	37	33	35	3,4	3,2	1
32	Shirxx	64	P	OD	12	2	Tidak ada	0,6	18	3,13	35	30	32,5	3,6	3,8	1
33	Siti Nixx	65	P	OD	24	4	Hipertensi	0,6	13	3,24	32	31	31,5	3,2	3,2	1
34	Senxxx	75	L	OS	36	6	Hipertensi	0,7	20	3,83	40	34	37	2,5	2,6	1
35	Marixxx	53	P	OS	12	2	Tidak ada	0,5	13	3,29	34	26	30	3,2	3	1
36	Ficexxx	60	P	OD	6	2	Tidak ada	0,4	18	3,24	34	32	33	4,2	4,3	2
37	Ratixx	64	P	OS	72	6	Tidak ada	0,6	14	3,45	39	38	38,5	2,5	2,6	1
38	Hawaxxx	59	P	OD	36	4	Tidak ada	0,7	14	3,31	42	36	39	4	4,2	2
39	Ludxxx	59	P	OD	4	1	Tidak ada	0,4	20	3,5	36	33	34,5	2,8	2,8	1
40	Paraxxx	68	L	OS	24	4	Tidak ada	1	19	3,18	35	34	34,5	5	5,1	2

No.	Nama	VA H1 LogMAR	TIO H1 mmHg	ACD H1 mm	ACA Temporal H1 degree	ACA Nasal H1 degree	ACA Avg H1 degree	VA H7 LogMAR	TIO H7 mmHg	ACD H7 mm	ACA Temporal H7 degree	ACA Nasal H7 degree	ACA Avg H7 degree	SE	BCVA LogMAR	Rumahnya Sakit	Ket
1	Silvxxx	0,3	8	3,22	27	21	24	0,1	17	3,16	35	32	33,5	-1,00	0	RSTC	
2	Sitl Naxxx	0,3	20	2,69	35	27	31	0,1	20	2,78	36	25	30,5	0,25	0	RSTC	
3	Bloxxx	0,4	14	2,92	33	27	30	0,2	16	2,92	34	30	32	0,25	0,1	RSTC	
4	Mahpuxxxx	0,3	13	3,1	30	30	30	0,2	16	3,1	34	36	35	-0,25	0	RSTC	
5	Naxxx	0,4	18	2,98	37	38	37	0,3	19	2,91	32	35	33,5	0,75	0	RSTC	
6	Naxxx	0,3	14	3,05	37	32	34,5	0,2	20	3,04	32	32	32	0,75	0	RSTC	
7	Muhaaxxx	0,1	10	3,57	35	30	32,5	0,1	10	3,45	36	34	35	0,25	0	RSTC	
8	Laxxx	0,2	10	3,2	42	37	39,5	0,1	12	3,08	37	21	29	-1,25	0	RSTC	
9	Isabdxxx	0,7	20	2,66	32	40	36	0,6	17	2,8	30	35	32,5	-2,50	0,3	RSTC	
10	Martxxxx	0,1	16	3,21	37	31	34	0,1	15	3,26	28	30	28,5	-0,25	0	RSTC	
11	Martxxxx	0,3	16	3,3	36	25	30,5	0,1	15	3,27	37	20	28,5	-0,75	0	RSTC	
12	Nurdxxx	0,2	20	2,87	33	30	31,5	0,2	16	2,89	31	28	29,5	0,50	0	RSTC	
13	Nurdxxx	0,2	17	2,9	36	31	33,5	0,2	18	2,92	34	28	31	0,00	0	RSTC	
14	Saxxxx	0,1	18	3,04	40	44	42	0,1	16	3,08	40	38	39	-1,00	0	JEC Orbita	
15	Saxxxx	0,3	16	3,42	38	37	37,5	0,3	14	3,35	36	33	34,5	-0,50	0	JEC Orbita	
16	Noxx	0,4	12	3,78	39	28	33,5	0,4	12	3,88	43	32	37,5	-1,00	0,1	JEC Orbita	
17	Aprx	0,7	18	3,78	40	37	38,5	0,6	14	3,79	41	27	39	-1,75	0,3	JEC Orbita	
18	Falixxx	0,3	15	3,47	32	28	30	0,3	16	3,49	32	27	29,5	0,375	0,1	JEC Orbita	
19	Ralixxx	0,3	16	3,42	36	32	34	0,3	11	3,4	37	32	34,5	1,25	0	JEC Orbita	
20	Abdxxx	0,6	20	3,92	34	36	35	0,2	18	3,86	43	39	41	-0,50	0	JEC Orbita	
21	Sitl Amxxx	0,4	16	3,34	38	35	36,5	0,4	16	3,3	32	34	33	-1,25	0,1	JEC Orbita	
22	Sr Asxx	0,1	12	3,32	38	39	38,5	0,1	12	3,45	35	35	35	0,00	0	JEC Orbita	
23	Normxxxx	0,7	14	3,23	28	32	30	0,6	12	3,02	31	30	30,5	-1,00	0,2	JEC Orbita	
24	Ferdxxxx	0	16	3,71	38	20	29	0	14	3,62	36	28	32	0,00	0	JEC Orbita	
25	Ferdxxxx	0,2	14	3,45	38	27	32,5	0,2	16	3,48	38	26	32	0,375	0	JEC Orbita	
26	Misdxxxxxx	0,2	17	3,4	33	30	31,5	0,2	16	3,34	30	30	30	0,75	0,1	JEC Orbita	
27	Haxxxx	0,2	17	3,54	37	36	36,5	0,1	19	3,26	34	32	33	0,50	0	JEC Orbita	
28	MTrxx	0,7	18	3,21	21	24	22,5	0,6	18	3,09	39	34	36,5	-2,25	0	JEC Orbita	
29	Basxxx	0,3	20	3,16	31	32	31,5	0,3	18	3,1	32	30	31	-2,00	0	JEC Orbita	
30	Yonxxx	0,2	11	3,57	40	32	36	0,2	12	3,24	38	36	37	2,00	0	JEC Orbita	
31	Jabaxxx	0,4	15	3,44	31	26	28,5	0,4	15	3,44	43	30	36,5	-1,00	0,1	JEC Orbita	
32	Shrxxx	0,4	17	3,09	32	34	33	0,4	17	3,12	32	31	31,5	-0,50	0	JEC Orbita	
33	Sitl Nixx	0,2	12	3,11	26	38	32	0,2	14	3,2	32	32	31,5	0,00	0	JEC Orbita	
34	Senxxx	0,4	14	3,72	42	43	42,5	0,4	14	3,8	38	36	37	1,25	0,4	JEC Orbita	
35	Martxxx	0,2	15	3,13	38	30	34	0,2	14	3,22	32	30	31	-0,75	0	JEC Orbita	
36	Flexxx	0,1	13	3,35	32	30	31	0,1	14	3,2	34	31	32,5	-0,50	0	JEC Orbita	
37	Raxxx	0,3	14	3,42	38	37	37,5	0,3	12	3,45	36	36	36	-0,25	0,1	JEC Orbita	
38	Hawaxxx	0,2	18	3,36	40	37	38,5	0,3	14	3,37	40	38	39	-0,75	0	JEC Orbita	
39	Ludxx	0,6	14	3,5	40	30	35	0,1	14	3,66	32	32	32	0,50	0	JEC Orbita	
40	Paraxxx	0,3	20	3,2	32	30	31	0,3	20	3,18	36	34	35	1,25	0,1	JEC Orbita	

Lampiran 4. Rekomendasi Persetujuan Etik



REKOMENDASI PERSETUJUAN ETIK

Nomor : 498/UN4.6.4.5.31/ PP36/ 2022

Tanggal: 12 September 2022

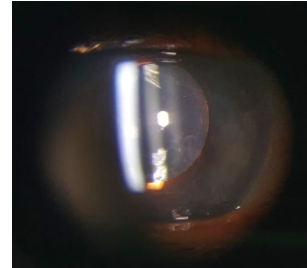
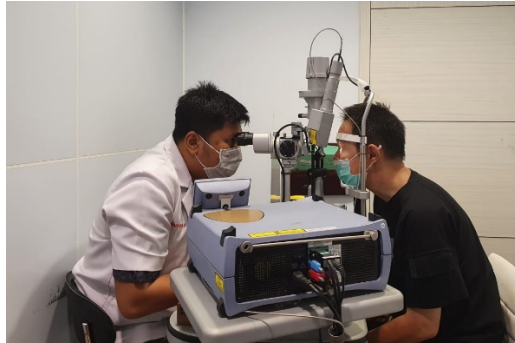
Dengan ini Menyatakan bahwa Protokol dan Dokumen yang Berhubungan Dengan Protokol berikut ini telah mendapatkan Persetujuan Etik :

No Protokol	UH22080433		No Sponsor Protokol	
Peneliti Utama	dr. Widodo Prima Utama		Sponsor	
Judul Peneliti	PENGARUH DIAMETER KAPSULOTOMI POSTERIOR LASER Nd: YAG TERHADAP PERUBAHAN KEDALAMAN BILIK MATA DEPAN, SUDUT IRIDOKORNEA, DAN LUARAN TAJAM PENGLIHATAN PADA PASIEN OPASIFIKASI KAPSUL POSTERIOR			
No Versi Protokol	1	Tanggal Versi	12 Agustus 2022	
No Versi PSP	1	Tanggal Versi	12 Agustus 2022	
Tempat Penelitian	RSUP dr. Tadjuddin Chalid dan Klinik Mata Orbita Makassar			
Jenis Review	<input type="checkbox"/> Exempted <input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal		Masa Berlaku	Frekuensi review lanjutan
			12 September 2022 sampai 12 September 2023	
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	

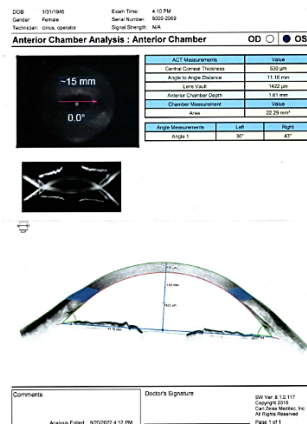
Kewajiban Peneliti Utama:

- Menyerahkan Amandemen Protokol untuk persetujuan sebelum di implementasikan
- Menyerahkan Laporan SAE ke Komisi Etik dalam 24 jam dan dilengkapi dalam 7 hari dan 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 5. Dokumentasi Penelitian



Mengukur diameter kapsulotomi posterior menggunakan *slit lamp*.



Menganalisa dan mengukur ACD dan ACA menggunakan AS-OCT Carl Zeiss, Cirrus HD OCT 5000.
