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KEMENTERIAN RISET TEKNOLOGI DAN PENDIDIKAN TINGGI  
UNIVERSITAS HASANUDDIN  
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Keputusan Protokol Amandemen

Nomor Protokol : UH18120966

Judul Protokol : Evaluasi Perubahan Jumlah Endotel Kornea, Ketebalan Kornea Sentral Dan Kedalaman Bilik Mata Depan Pada Pasien Posterior Capsular Opacity Pasca Nd: Yag Laser	
Nama Peneliti: dr.Natalia Stevanie	
Institusi :Departemen I.K Mata	
Review Protokol Amandemen Ya                      Tidak <input type="checkbox"/> <input checked="" type="checkbox"/>	Tanggal review sebelumnya
Keputusan	<input checked="" type="checkbox"/> Disetujui (1) <input type="checkbox"/> Disetujui dengan Modifikasi amandemen dan informed consent <input type="checkbox"/> Dihentikan, sambil menunggu informasi lanjut (3) <input type="checkbox"/> Butuh informasi lanjut, tetap berjalan dengan protokol sebelumnya (4) <input type="checkbox"/> Ditolak, bisa lanjut dengan persetujuan sebelumnya (5)
Tempat Penelitian :	Klinik Mata Orbita Makassar
No.	Nama Reviewer
	Keputusan
	1   2   3   4   5
1	<input checked="" type="checkbox"/>

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Lampiran 1.

### NASKAH PENJELASAN PADA SUBYEK

Selamat pagi/siang bapak/ibu....., saya dr. Natalia Stevanie, dokter peserta program pendidikan dokter spesialis mata pada Bagian Ilmu Kesehatan Mata, Fakultas Kedokteran Universitas Hasanuddin. Saya akan melakukan penelitian mengenai evaluasi perubahan jumlah endotel kornea, ketebalan kornea sentral dan kedalaman bilik mata depan pada pasien posterior capsular opacity pasca Nd: YAG laser

Katarak merupakan suatu masalah global yang memberi gambaran penurunan fungsi penglihatan sehingga menjadi salah satu penyebab kebutaan. Penyebab kebutaan terbanyak di seluruh dunia adalah katarak (51%), glaukoma (8%) dan age related macular degeneration (5%). Salah satu komplikasi setelah operasi katarak jangka panjang yang sering didapatkan yaitu posterior capsular opacification (PCO) atau yang biasa disebut sebagai katarak sekunder. Penurunan visus yang diakibatkan oleh PCO sekitar 20-40 % pada pasien setelah operasi katarak.

Kami mengikutsertakan Bapak/Ibu dalam penelitian ini dengan tujuan mengetahui seberapa besar perubahan jumlah endotel kornea, ketebalan kornea sentral dan kedalaman bilik mata depan (BMD) pada pasien PCO pasca Nd: YAG laser. Partisipasi bapak/ibu dalam penelitian ini diharapkan dapat menambah informasi baik bagi dokter yang melakukan operasi maupun bagi pasien sendiri untuk mengetahui seberapa besar pengaruh Nd: YAG laser perubahan jumlah endotel kornea, ketebalan kornea sentral dan kedalaman BMD.

Pada hari pemeriksaan, kami akan mencatat identitas bapak/ibu (nama, alamat, umur). Sebelum dilakukan operasi akan dilakukan pemeriksaan bagian depan bola mata, tekanan bola mata, pemeriksaan jumlah endotel kornea dan ketebalan kornea sentral dengan menggunakan alat mikroskop spekular dan pemeriksaan sudut bilik mata depan

dengan menggunakan alat anterior segment optical coherence tomography (AS-OCT). Setelah itu, kemudian pasien akan menjalani kapsulotomi dengan menggunakan Nd: YAG laser sesuai jadwal dan prosedur yang berlaku. Satu jam setelah kapsulotomi dengan Nd: YAG laser, kami akan kembali melakukan pemeriksaan bagian depan bola mata dengan menggunakan alat slit lamp, pengukuran tekanan bola mata, pemeriksaan jumlah endotel kornea dan ketebalan kornea sentral dengan menggunakan alat mikroskop spekulat, dan pemeriksaan sudut bilik mata depan dengan AS-OCT. Pemeriksaan yang sama akan dilakukan pada hari ketujuh setelah operasi. Pemeriksaan dengan mikroskop spekulat dan AS-OCT akan dilakukan di Klinik Mata Orbita Makassar tanpa perlu membayar (biaya akan ditanggung peneliti).

Bapak/ibu diberikan kesempatan untuk menanyakan segala sesuatu yang belum jelas serta mendapatkan keterangan dari peneliti di Bagian Ilmu Kesehatan Mata atau di nomor telepon peneliti 082190369266.

Risiko yang akan terjadi akibat penelitian ini tidak ada, karena tidak dilakukan intervensi tambahan pada bola mata. Keuntungan mengikuti penelitian ini adalah bapak/ibu dapat mengetahui jumlah endotel kornea, ketebalan kornea sentral dan perubahan kedalaman BMD. Apabila dari hasil penelitian ditemukan jumlah endotel kornea berkurang, ketebalan kornea sentral meningkat dan kedalaman BMD menjadi lebih dangkal, maka informasi ini dapat menjadi sangat penting untuk mengedukasi penderita untuk pakai obat secara teratur dan kontrol rutin.

Partisipasi dari bapak/ibu pada penelitian ini adalah sukarela. Bapak/ibu bisa berkonsultasi dengan dokter bapak/ibu mengenai status kesehatan bapak/ibu sebelum mengikuti penelitian ini.

Tidak akan terjadi perubahan mutu pelayanan dari dokter bapak/ibu bila bapak/ibu tidak bersedia mengikuti penelitian ini. Bapak/ibu tetap akan mendapatkan pelayanan kesehatan standar rutin sesuai penyakit mata bapak/ibu yang selama ini ditempuh seperti pemeriksaan sebelum menjalani operasi, prosedur operasi, konsultasi berkala setelah operasi, pemeriksaan laboratorium serta pemberian obat lain yang diperlukan.

Pada penelitian ini identitas bapak/ibu disamarkan, hanya dokter peneliti dan anggota komisi etik yang bisa melihat data anak bapak/ibu. Kerahasiaan data bapak/ibu sepenuhnya akan dijamin. Bila data akan dipublikasikan kerahasiaan akan tetap dijaga.

Data pada penelitian ini akan dikumpulkan dan disimpan di file manual atau elektronik, diaudit, diproses dan dipresentasikan pada:

- Forum ilmiah Program Pasca Sarjana Bagian Ilmu Kesehatan Mata



- Publikasi pada jurnal ilmiah dalam maupun luar negeri

Jika bapak/ibu setuju untuk berpartisipasi, diharapkan menandatangani surat persetujuan mengikuti penelitian. Atas kesediaan dan kerjasamanya diucapkan terima kasih.

**Identitas peneliti** : dr. Natalia Stevanie

**Alamat** : Kompleks bumi tamalanrea permai blok M no 130

**Telp.** : 082190369266

DISETUJUI OLEH KOMISI PENELITIAN  
KESEHATAN FAKULTAS KEDOKTERAN UNHAS

TGL.....2018



**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**

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

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**e-mail:agussalimbukhari@yahoo.com**

Lampiran 2.

**FORMULIR PERSETUJUAN**

Saya yang bertanda tangan di bawah ini :

Nama : ..... Umur : ..... tahun

Alamat : .....

Telepon/HP : .....

Menyatakan bersedia untuk berpartisipasi pada penelitian ini yang berjudul :

**“ EVALUASI PERUBAHAN JUMLAH ENDOTEL KORNEA, KETEBALAN KORNEA SENTRAL DAN KEDALAMAN BILIK MATA DEPAN PADA PASIEN *POSTERIOR CAPSULAR OPACITY* PASCA *Nd: YAG LASER* “**

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

Saksi I

(.....)

Saksi II

(.....)

Penanggung jawab penelitian:

dr.Natalia Stevanie

Kompleks bumi tamalanrea permai blok M no 130

082190369266

Penanggung jawab medik :

Dr.Hamzah, Sp.M(K)

Jl. Pendidikan D4/15. Kompleks IKIP

08164384460

## DATA HASIL PENELITIAN

## EVALUASI PERUBAHAN JUMLAH ENDOTEL KORNEA, KETEBALAN KORNEA SENTRAL DAN KEDALAMAN BILIK MATA DEPAN PADA PASIEN POSTERIOR CAPSULAR OPACITY PASCA Nd:YAG LASER

No	Nama	Umur (tahun)	Jenis kelamin	Tipe PCO	Pre Nd:YAG Laser				1 jam Post Nd:YAG Laser				1 minggu Post Nd:YAG Laser			Diameter kapsulotomi (mm)	Nd:YAG Laser (mJ)			
					TIO (mm Hg)	CCT ( $\mu$ m)	ECD (sel/mm <sup>2</sup> )	BMD (mm)	TIO (mm Hg)	CCT ( $\mu$ m)	ECD (sel/mm <sup>2</sup> )	BMD (mm)	TIO (mm Hg)	CCT ( $\mu$ m)	ECD (sel/mm <sup>2</sup> )		BMD (mm)	Energi	shot	Total dosis
1	Aris	40	Lk	fibrosis	17	517	2272	2.58	16	535	2035	2.44	18	532	1950	2.44	4	3.1	20	70
2	Sukma	54	Pr	fibrosis	12	516	2243	3.23	13	546	2460	2.55	10	541	2440	2.87	3.9	2.7	17	52
3	Fanny	60	Pr	elschnig	13	533	2767	2.27	15	544	2212	2.18	14	539	2212	2.17	3.7	1.7	11	20
4	Jacky	65	Lk	fibrosis	13	503	2121	3.02	14	513	1875	2.94	14	513	1690	2.94	3.8	3	13	43
5	Mustari	54	Lk	elschnig	13	505	2556	3.43	15	515	2500	3.4	15	518	2470	3.38	4.1	1.9	13	30
6	Yulia	59	Pr	elschnig	12	510	1884	3.29	12	538	1807	3.0	13	527	1745	2.7	3.9	1.6	15	28
7	Maryam	70	Pr	fibrosis	15	534	2151	3.05	17	541	2005	3.45	16	538	1952	3.3	4.2	3	23	81
8	Medi	69	Lk	fibrosis	14	472	2197	3.41	14	500	2099	3.05	12	486	2037	3.05	3.8	2.8	13	40
9	Norma	63	Pr	elschnig	18	520	2633	3.51	18	533	2601	3.26	17	529	2597	3.25	3.9	1.7	15	30
10	Siti	65	Pr	elschnig	15	513	2387	3.69	16	525	2275	3.4	14	521	2371	3.38	4	1.9	19	41
11	Jelmi	61	Lk	elschnig	19	505	2601	3.01	20	513	2562	2.68	18	509	2540	2.68	4	1.5	12	21
12	Elisabet	70	Pr	elschnig	14	537	2461	3.03	14	549	2303	2.36	12	547	2279	2.35	3.8	2.1	16	45
13	Husaeni	47	LK	fibrosis	13	521	1597	3.41	11	535	1527	3.14	12	532	1456	3.16	4	2.9	21	69
14	Bombong	55	Pr	elschnig	11	524	2873	2.51	12	536	2769	2.4	10	536	2866	2.43	4.1	2.2	21	60
15	Pja	70	Lk	fibrosis	15	505	2406	3.15	16	516	2383	3.0	14	517	2378	3	4	3.2	24	85
16	Imam	58	Lk	fibrosis	16	545	2393	3.18	17	573	2381	2.95	15	567	2378	2.92	3.9	3.1	23	82