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KEMENTERIAN RISET, TEKNOLOGI DAN PENDIDIKAN TINGGI
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REKOMENDASI PERSETUJUAN ETIK

Nomor : 438/UN4.6.4.5.31/ PP36/ 2019

Tanggal: 14 Juni 2019

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

No Protokol	UH19050298		
Peneliti Utama	dr. Ganesa Wardana	Sponsor	
Judul Peneliti	Faktor Resiko Oftalmoplegia Pada Diabetes Melitus		
No Versi Protokol	1	Tanggal Versi	17 Mei 2019
No Versi PSP	1	Tanggal Versi	17 Mei 2019
Tempat Penelitian	RS Universitas Hasanuddin Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal	Masa Berlaku 14 Juni 2019 sampai 14 Juni 2020	Frekuensi review lanjutan
Wakil Ketua Komisi Etik Penelitian	Nama Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K)	Tanda tangan 	
Sekretaris Komisi Etik Penelitian	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 protokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan



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

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

e-mail:agussalimbukhari@yahoo.com

Lampiran 1.

NASKAH PENJELASAN PADA SUBYEK

Faktor Resiko Oftalmoplegia pada Diabetes Melitus

Assalamualaikum Wr. Wb/ Selamat pagi bapak/ ibu/ saudara(i), Saya Ganesa Wardana dari bagian Ilmu Kesehatan Mata Unhas. Kami bermaksud untuk melakukan penelitian mengenai hubungan faktor resiko (usia, gender, tipe dan durasi penyakit serta ada atau tidaknya penyakit penyerta) pada pasien Diabetes Melitus, dengan terjadinya oftalmoplegia diabetik. Kami melakukan penelitian ini karena komplikasi neuropati yang menyebabkan oftalmoplegia merupakan salah satu dari komplikasi terbanyak dari Diabetes Melitus. Mekanisme yang menyebabkan komplikasi diabetes Melitus ini melibatkan beberapa faktor resiko. Meskipun penelitian tentang faktor resiko oftalmoplegia pada pasien diabetes telah banyak dilakukan pada negara-negara maju, namun data mengenai oftalmoplegia diabetes belum pernah dilakukan di Makassar. Karenanya, kami terdorong untuk mengevaluasi adanya faktor-faktor resiko yang ada pada pasien diabetes yang dapat menyebabkan terjadinya oftalmoplegia. Diharapkan dengan penelitian ini, selain menurunkan indeks gula darah, faktor resiko lain juga dapat diantisipasi untuk mencegah terjadinya oftalmoplegia diabetik.

Pemeriksaan yang dilakukan merupakan bagian dari pemeriksaan rutin di poliklinik Endokrin. Semua pasien yang terdiagnosa Diabetes Melitus, dilakukan pencatatan data yang dikumpulkan dari adalah: jenis kelamin, usia, ketajaman visual, jenis dan durasi DM, adanya penyakit penyerta: hipertensi, hyperlipidemia dan penyakit arteri coroner. Pasien yang memenuhi kriteria inklusi dimasukan sebagai sampel penelitian. Diantara pasien DM yang mempunyai gejala oftalmoplegia atau pengelihatan ganda (diplopia) akan dilakukan pemeriksaan tambahan di poliklinik mata. Data tambahan yang diperiksa yaitu saraf kranial yang terlibat, tanggal onset kelumpuhan saraf kranial, gejala awal, terutama adanya rasa sakit/ nyeri, frekurensi dan lateralitas

kelumpuhan saraf kranial, kehadiran keterlibatan pupil pada parese saraf kranial III, dan waktu untuk terjadinya resolusi kelumpuhan. Semua data yang didapat dimasukan ke dalam tabel, untuk selanjutnya dilakukan analisa statistik untuk mengetahui hubungan faktor resiko pada pasien Diabetes Melitus dengan terjadinya oftalmoplegia diabetik.

Kami sangat mengharapkan kesediaan Bapak/Ibu untuk dapat ikut serta dalam penelitian ini. Penelitian ini bersifat sukarela tanpa ada kompensasi maupun paksaan, sehingga bapak/ibu sekalian dapat menolak untuk ikut dalam penelitian ini. Bapak/Ibu juga dapat menolak atau mengundurkan diri dari penelitian ini kapan saja jika terdapat hal-hal yang tidak berkenaan terhadap bapak/ibu dan tidak akan dikenakan sanksi apapun. Pengunduran diri tersebut tidak akan mengurangi perubahan mutu pelayanan dari dokter.

Bila masih ada hal-hal yang ingin Bapak/Ibu ketahui, maka Bapak/Ibu dapat bertanya atau meminta penjelasan pada kami di Bagian Ilmu Kesehatan Mata RS UNHAS, atau secara langsung melalui nomor telepon saya: dr. Ganesa Wradana, 08115443436

Semua data dari penelitian ini akan dicatat dan dipublikasikan tanpa membuka data pribadi pasien dan jika akan dipublikasi, kami akan meminta persetujuan dari Bapak/Ibu. Data pada penelitian ini akan dikumpulkan dan disimpan dalam *file* manual dan elektronik, diaudit dan diproses serta dipresentasikan pada:

- Forum ilmiah Departemen Ilmu Kesehatan Mata, FK - Universitas Hasanuddin
- Publikasi pada jurnal ilmiah dalam negeri

Bila bapak/ibu setuju maka kami berharap bapak/ibu menandatangani surat persetujuan setelah mengikuti penjelasan ini.

Atas kesediaan dan kerjasamanya kami sampaikan terima kasih.

Identitas Peneliti

Nama : Ganesa Wardana

Alamat : BTN Hamsi Blok P no 7 Jl.Perintis kemerdekaan III, Tamalanrea Makassar

Hp : 08115443436

DISETUJUI OLEH KOMISI
PENELITIAN KESEHATAN
FAKULTAS KEDOKTERAN UNHAS
TGL..... 2019



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

“Faktor Resiko Oftalmoplegia pada Diabetes Melitus “

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

. (.....)

No	Nama	RM	jenis kelamin		Usia	Parese		Jenis Parese			Visus		Jenis DM		durasi DM (tahun)	HT	Dislipid	CAD	RD	ket
			Perempuan	Laki-laki		Ya	Tidak	N III	N IV	N VI	od	os	type I	type II						
1	ronawati	105710	1	0	60	1	0	0	0	1	20/100	20/80	0	1	10	1	0	0	0	
2	Nichwan	117306	0	1	32	1	0	0	0	1	20/30	20/30	0	1	12	0	0	0	1	
3	A. Tenri jaya	101071	1	0	46	1	0	0	0	1	20/60	20/40	0	1	10	0	0	0	0	
4	Satyla	101716	1	0	50	1	0	1	0	0	20/40	20/60	0	1	10	0	0	0	0	ct dbn
5	Nur Thita	103921	1	0	24	1	0	0	0	1	20/60	20/60	0	1	1	0	0	0	0	
6	Kursiah	111111	1	0	25	1	0	0	0	1	20/20	20/20	0	1	1	0	0	0	0	
7	Rudy Ferdy Gosal	106530	0	1	34	1	0	0	0	1	20/20	20/20	0	1	13	1	0	0	0	
8	Nursiah	100892	1	0	48	1	0	0	0	1	20/200	20/200	0	1	5	1	1	0	0	
9	muh. Tahir	111638	0	1	63	1	0	0	0	1	20/20	20/20	0	1	5	1	0	0	0	
10	Mariati	112544	0	1	26	1	0	0	0	1	20/20	20/20	0	1	1	0	0	0	0	
11	Sulfadli	47055	0	1	54	0	1	0	0	0	20/40	20/30	0	1	9	0	0	0	0	
12	Sri susyanti	12193	1	0	55	0	1	0	0	0	20/30	20/30	0	1	15	0	1	0	0	
13	Herianti	14531	1	0	37	0	1	0	0	0	20/20	20/20	0	1	6	0	0	0	0	neuropati +
14	Muttiara	19485	1	0	59	0	1	0	0	0	20/60	20/60	0	1	13	1	1	0	0	
15	H. Lagiono	29281	0	1	63	0	1	0	0	0	20/200	20/200	0	1	5	1	0	0	0	
16	Karsa Eka Lolo	56874	0	1	40	0	1	0	0	0	20/20	20/20	0	1	4	1	1	1	0	kaki diabetik
17	Rohana Toding	58461	1	0	55	0	1	0	0	0	20/60	20/40	0	1	3	1	0	0	0	
18	Hj. A. Munirah s	36678	1	0	57	0	1	0	0	0	20/60	20/60	0	1	15	1	1	0	0	
19	Deby Farah diba	53370	1	0	38	0	1	0	0	0	20/20	20/20	0	1	10	0	1	0	0	
20	St. Aisyah Abubakar	48519	1	0	71	0	1	0	0	0	20/200	20/200	0	1	20	1	1	1	0	
21	Lastari	55521	1	0	72	0	1	0	0	0	20/400	20/400	0	1	4	1	0	0	0	
22	Siti Nurbaya	31087	1	0	58	0	1	0	0	0	20/60	20/60	0	1	4	1	1	0	0	
23	dr. Musatar	39787	0	1	61	0	1	0	0	0	20/100	20/100	0	1	10	1	1	1	0	
24	Rugaya manggala	51876	1	0	64	0	1	0	0	0	20/40	20/40	0	1	10	1	1	0	0	ckd
25	Sitti sulfangru	6097	1	0	49	0	1	0	0	0	20/40	20/40	0	1	10	0	0	0	0	
26	muliana nasir	10430	1	0	54	0	1	0	0	0	20/100	20/60	0	1	15	0	0	0	0	
27	H. Galib sjamsi	91775	0	1	79	0	1	0	0	0	20/400	20/400	0	1	17	1	1	1	0	
28	Fatimah	92069	1	0	74	0	1	0	0	0	20/200	20/400	0	1	10	1	0	0	0	riw.stroke
29	m. Arfa	94502	0	1	17	0	1	0	0	0	20/20	20/20	1	0	1	0	0	0	0	
30	H. Saini	108255	0	1	59	0	1	0	0	0	20/30	20/30	0	1	11	0	0	0	0	nefropati
31	Namri	110119	1	0	65	0	1	0	0	0	20/200	20/200	0	1	6	1	0	1	0	
32	wardah	110251	1	0	56	0	1	0	0	0	20/100	20/60	0	1	10	0	0	0	0	
33	Ahmad munir	110464	0	1	50	0	1	0	0	0	20/40	20/40	0	1	4	0	0	0	0	
34	dr. H. Nurdings	110536	0	1	63	0	1	0	0	0	20/200	20/200	0	1	10	1	1	1	0	
35	Risma	65436	1	0	35	0	1	0	0	0	20/20	20/20	0	1	8	0	0	0	0	neuropati +
36	Baharuddin	109282	0	1	60	0	1	0	0	0	20/60	20/40	0	1	10	1	1	0	0	
37	Dahlia	109391	1	0	51	0	1	0	0	0	20/40	20/40	0	1	5	0	0	0	0	
38	Rahmatia	86601	1	0	57	0	1	0	0	0	20/60	20/40	0	1	15	0	0	0	0	neuropati +
39	Irene Intan	85545	1	0	48	0	1	0	0	0	20/400	1/300	0	1	13	1	0	0	1	
40	Yunius Mohubu	101140	0	1	60	0	1	0	0	0	20/30	20/30	0	1	10	0	0	0	0	
41	Alim Usman	99488	0	1	47	0	1	0	0	0	20/30	20/30	0	1	5	0	0	0	0	
42	Benawaty	101010	1	0	58	0	1	0	0	0	20/40	20/40	0	1	10	0	0	0	0	
43	ir. Amrani samad	99953	0	1	54	0	1	0	0	0	20/30	20/40	0	1	15	1	1	1	0	
44	Naima	81488	1	0	54	0	1	0	0	0	20/30	20/30	0	1	10	1	0	0	0	
45	Djuriah Adam	91867	1	0	64	0	1	0	0	0	20/200	20/200	0	1	10	0	0	0	0	
46	P. Sudirman	78232	0	1	57	0	1	0	0	0	20/400	20/200	0	1	20	1	1	1	1	ckd
47	drs. Abd. Rahman	108870	0	1	53	0	1	0	0	0	20/200	20/200	0	1	7	1	0	0	0	
48	Dg. Nompo	107113	0	1	54	0	1	0	0	0	20/60	20/40	0	1	10	0	0	0	0	
49	Kamsiah	107192	1	0	53	0	1	0	0	0	20/30	20/30	0	1	1	0	0	0	0	
50	usman	106739	0	1	49	0	1	0	0	0	20/30	20/30	0	1	10	0	0	0	0	
51	A. Roki	74968	1	0	64	0	1	0	0	0	20/60	20/60	0	1	5	1	1	0	0	
52	Asnawati	104632	1	0	53	0	1	0	0	0	20/40	20/40	0	1	1	0	0	1	0	
53	Sirajuddin	105482	0	1	58	0	1	0	0	0	20/100	20/60	0	1	10	0	0	0	0	neuropati +

54	murida dg sangka	111538	1	0	56	1	0	1	0	0	20/100	20/200	0	1	10	0	1	0	0	
55	Irwan	112728	0	1	35	1	0	1	1	0	20/20	20/20	0	1	5	0	0	0	0	
	n		32	23		12	43	3	1	9			1	54		26	17	10	3	

n Sampel: 55
 Perempuan: 32
 Laki-laki: 23
 n Parese: 12 usia >50: 4 usia<50: 8 Perempuan 7 Laki-laki 5 >10th: 6 <10th: 6
 n tidak parese 43
 parese N III 3
 parese N IV 1
 parese N VI 9
 Parese multiple 1
 DM tipe I 1
 DM tipe II 54
 HT 26
 Dislipidemia 17
 CAD 10
 Retinopati 3
Durasi DM >10th 33
 Durasi DM <10th 22
 Usia >50th 38
 Usia <50th 17

 Parese DM >10th 6
 Parese DM <10th 6

 parese+HT 4
 parese+dislipid 2
 parese+CAD 0
 parese+RD 1