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Lampiran 1 Formulir Penelitian

Seluruh data yang diperoleh berdasarkan hasil anamnesis, pemeriksaan fisis dan endoskopi laring yang kemudian dituliskan dalam formulir ini

Nomor Sampel Penelitian :

Tanggal Pemeriksaan :

No. RM :

Nama :

Umur :

Jenis Kelamin :

Anamnesis :

Pemeriksaan Fisis :

Reflux Symptoms Index (RSI)

0 = tidak ada keluhan 5 = keluhan sangat berat							
1	Suara serak atau bermasalah dengan suara anda	0	1	2	3	4	5
2	Membersihkan tenggorokan anda	0	1	2	3	4	5
3	Lendir Tenggorokan berlebih atau postnasal drip (terasa seperti ada yang mengalir dari hidung ke tenggorokan)	0	1	2	3	4	5
4	Kesulitan menelan makanan, cairan atau pil	0	1	2	3	4	5
5	Batuk setelah makan atau setelah berbaring	0	1	2	3	4	5
6	Kesulitan bernafas atau adanya episode tersedak	0	1	2	3	4	5
7	Batuk yang mengganggu	0	1	2	3	4	5
8	Sensasi sesuatu yang menempel di tenggorokan anda, atau terasa seperti ada yang mengganjal di tenggorokan	0	1	2	3	4	5
9	Dada terasa panas, nyeri dada, gangguan pencernaan atau asam lambung	0	1	2	3	4	5
Total							

Refluks Finding Score (RFS)

No	Temuan	Nilai
1	Edema subglotis	0 = Tidak ada 2 = Ada
2	Obliterasi ventricular	2 = Parsial 4 = Lengkap
3	Eritema/hiperemis	2 = Hanya arytenoid 4 = Difusa
4	Edema pita suara	1 = Ringan 2 = Sedang 3 = Berat 4 = Polipoid
5	Edema laring difusa	1 = Ringan 2 = Sedang 3 = Berat 4 = Obstruksi
6	Hipertrofi komisura posterior	1 = Ringan 2 = Sedang 3 = Berat 4 = Obstruksi
7	Jaringan granuloma/granulasi	0 = Tidak ada 2 = Ada
8	Mukus endolaringeal kental	0 = Tidak ada 2 = Ada
TOTAL		

Pemeriksaan Hematologi dan kadar vitamin B12 serum

Hasil	Hematologi	Nilai
	Hemoglobin(gr/dl)	
	MCV (fL)	
	MCH (pg)	
	MCHC (gr/dl)	
	Vitamin B12(pg/ml)	

KARTU KONTROL PENGGUNAAN OBAT PROTON PUMP INHIBITOR
(Omeprazole 20 mg/12 Jam/Oral)

Nomor Sampel Penelitian :

Tanggal Mulai Terapi :

Pemeriksa :

Rumah Sakit :

No. RM :

Nama :

Jenis Kelamin :

	1	2	3	4	5	6	7	8	9	10
Pagi										
Malam										

	11	12	13	14	15	16	17	18	19	20
Pagi										
Malam										

	21	22	23	24	25	26	27	28	29	30
Pagi										
Malam										

Lampiran 2 Surat Rekomendasi Persetujuan Etik

KEMENTERIAN PENDIDIKAN, KEBUDAYAAN, RISET DAN TEKNOLOGI

UNIVERSITAS HASANUDDIN FAKULTAS KEDOKTERAN

KOMITE ETIK PENELITIAN UNIVERSITAS HASANUDDIN

RSPN UNIVERSITAS HASANUDDIN

RSUP Dr. WAHIDIN SUDIROHUSODO MAKASSAR

Sekretariat : Lantai 2 Gedung Laboratorium Terpadu

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

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REKOMENDASI PERSETUJUAN ETIK

Nomor : 314/UN4.6.4.5.31/ PP36/ 2022

Tanggal: 24 Juni 2022

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

No Protokol	UH22040199	No Sponsor Protokol	
Peneliti Utama	dr. Foppi Puspitasari	Sponsor	
Judul Peneliti	Pengaruh Terapi Proton Pump Inhibitor terhadap Kadar Vitamin B12 Serum dan Parameter Hematologi Dalam Darah Penderita Refluks Laringofaring		
No Versi Protokol	2	Tanggal Versi	17 Juni 2022
No Versi PSP	2	Tanggal Versi	17 Juni 2022
Tempat Penelitian	RSUP Dr. Wahidin Sudirohusodo Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Fullboard	Masa Berlaku 24 Juni 2022 sampai 24 Juni 2023	Frekuensi review lanjutan
Ketua KEP Universitas Hasanuddin	Nama Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K)		
Sekretaris KEP Universitas Hasanuddin	Nama dr. Agussalim Bukhari, M.Med.,Ph.D.,Sp.GK (W)		

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

Lampiran 3 Dokumentasi Kegiatan



Lampiran 4 Data Dasar Penelitian

NO	Nama	Minggu Ke	RM	RSI	RFS	HB	MCV	MCH	MCHC	Serum Vit. B12
1	NN	0	935762	13	15	13,3	81	27	33	823
	25/04/75	6		8	6	13,1	81	28	32	825
		12		5	6	13	80	27	33	753
2	MR/L	0	942905	14	11	11,2	78	24	31	587
	07/06/00	6		13	7	11,2	79	25	31	658
		12		6	6	11,1	78	24	30	738
3	BD/P	0	941570	11	16	14	89	31	35	496
	21/08/80	6		13	7	14,1	90	31	36	523
		12		6	5	14,1	89	31	36	502
4	RK/P	0	941268	17	8	14	85	28	33	926
	02/08/76	6		13	8	14	87	30	33	738
		12		4	6	14,1	87	31	35	858
5	AM /L	0	945983	23	17	14	89	31	35	569
	12/05/70	6		11	9	14	90	31	36	638
6	JD/P	0	946406	17	14	12	86	29	34	738
	06/10/93	6		12	3	12	85	29	33	690
		12		5	1	12,9	86	29	34	869
7	SH/L	0	949115	17	16	12	89	31	35	747
	09/04/68	6		15	14	12,3	92	33	35	838
		12		9	7	12,8	95	33	34	1265
8	NL /L	0	950885	13	7	14,5	85	30	35	1213
	19/07/76	6		11	5	14,5	86	29	33	838
		12		8	5	13,7	86	29	34	768
9	AD/L	0	951513	17	13	17,2	83	28	34	543
	07/07/77	6		7	3	17	84	28	33	690
		12		5	3	17	83	27	33	593
10	HWi/P	0	986076	17	13	12,7	91	31	34	951
	28/01/75	6		8	6	12,5	87	30	33	837
		12		5	1	12,6	85	29	34	526
11	ES /L	0	945981	15	13	14	85	28	33	475
	10/04/50	6		11	8	14	86	29	34	347
		12		8	6	13,5	86	29	33	278
12	SL /L	0	911279	17	8	12,5	90	30	32	361
	28/01/54	6		12	7	12,3	84	29	34	285
		12		5	4	12,5	87	30	33	563
13	EB / P	0	949246	26	14	13	93	32	35	790

	10/12/63	6		23	11	12,6	99	33	34	728
		12		7	1	12,5	94	32	35	659
14	NW /P	0	951686	17	13	14	90	31	34	1398
	31/10/63	6		8	14	13,8	90	30	34	1257
		12		5	4	13,8	86	29	34	983
15	IS /L	0	929381	19	7	17	85	30	35	951
	01/07/89	6		8	7	16,5	83	29	34	874
		12		5	4	15,8	80	26	36	769
16	KK /P	0	938906	17	9	13,8	69	21	30	1373
	29/06/85	6		11	4	13,4	69	22	32	1270
		12		7	3	13,3	70	22	31	1022
17	NL /P	0	955262	19	9	14,3	80	29	37	1374
	02/03/77	6		9	4	14,1	81	29	35	1337
		12		5	3	14,1	87	29	34	1022
18	HR /P	0	957013	23	13	12,3	91	30	33	428
	01/12/73	6		7	8	11,5	87	29	33	358
		12		9	7	10,9	85	27	32	323
19	MH /P	0	78687	15	9	14,2	87	29	34	604
	28/06/70	6		9	4	14,3	80	29	37	747
		12		6	3	14,2	87	28	33	723
20	NS /P	0	985940	13	12	11	86	28	33	1022
	18/11/78	6		10	8	11,2	87	30	34	999
		12		5	3	11,1	86	30	34	706