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LAMPIRAN

KEMENTERIAN RISET, TEKNOLOGI, DAN PENDIDIKAN TINGGI INDONESIA



**UNIVERSITAS HASANUDDIN FAKULTAS KEDOKTERAN
KOMITE ETIK PENELITIAN KESEHATAN**

Sekretariat : Lantai 3 Gedung Laboratorium Terpadu

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Lampiran 1 :

NASKAH PENJELASAN UNTUK MENDAPAT PERSETUJUAN DARI SUBYEK PENELITIAN

Selamat pagi bapak/ibu/saudara, saya dr. Indra Irawan dari Bagian Ilmu Kesehatan Telinga Hidung dan Tenggorokan RS. Wahidin Sudirohusodo, yang akan melakukan penelitian tentang perbandingan kadar vitamin D pada pasien COVID -19 Konfirmasi asimtomatis dengan pasien COVID – 19 konfirmasi simtomatis di Makassar akan mengajukan pertanyaan berupa anamnesis tentang penyakit yang anda derita sekarang dan melakukan .

Kami bermaksud untuk mengadakan penelitian dengan judul:

Perbandingan kadar vitamin D pada pasien COVID -19 Konfirmasi asimtomatis dengan pasien COVID – 19 konfirmasi simtomatis di Makassar. Pemeriksaan ini dilakukan untuk mengetahui Kadar vitamin D dalam darah pasien COVID-19. Untuk itu kami meminta kesediaan bapak/ibu/saudara untuk mengizinkan kami melakukan pengambilan darah pada vena mediana cubiti untuk selanjutnya dilakukan pemeriksaan kadar vitamin D pada serum darah yang sudah diambil.

Prosedur pemeriksaan kadar vitamin D pada pasien COVID-19 konfirmasi : Dilakukan anamnesis pada pasien COVID-19 konfirmasi, dilanjutkan dengan melakukan pengambilan darah pada vena mediana cubiti untuk selanjutnya dilakukan pemeriksaan kadar vitamin D pada serum darah yang sudah diambil.

Bapak/ibu/saudara/adik berhak menolak ikut serta atau menjawab pertanyaan tanpa resiko kehilangan hak pelayanan kesehatan yang harus diterima. Penolakan dan pengunduran diri dari penelitian tidak akan menghilangkan hak pelayanan kesehatan penderita yang harus diterima. Resiko pengambilan darah untuk mendapatkan serum darah adalah hematoma pada tempat pengambilan darah, perdarahan, rasa nyeri, serta rasa tidak nyaman. Tidak diberi kompensasi khusus pada pasien, namun

semua biaya pemeriksaan adalah tanggungan kami sepenuhnya serta hasil pemeriksaan yang kami dapatkan akan kami jamin kerahasiaannya.

Data yang kami peroleh dari penelitian ini akan bermanfaat untuk memberikan informasi ilmiah mengenai kadar vitamin D pada konfirmasi COVID-19 di Makassar, sebagai data dasar dan acuan bagi penelitian mengenai jumlah suplementasi vitamin D yang diperlukan pada pasien COVID-19 konfirmasi di Makassar, serta membantu klinisi dalam memutuskan perlu atau tidaknya pemberian suplementasi vitamin D selama perawatan pada pasien COVID-19 konfirmasi di Makassar.

Bila masih ada hal-hal yang ingin diketahui atau masih ada hal-hal yang belum jelas, maka bapak/ibu/saudara/adik bisa bertanya atau meminta penjelasan pada kami secara langsung atau melalui telepon.

Semua data dari penelitian ini akan dicatat dan dipublikasikan tanpa membuka data pribadi bapak/ibu/saudara/adik. Data penelitian ini akan dikumpulkan dan disimpan dalam file manual atau elektronik, dan diproses serta dipresentasikan dalam :

Forum ilmiah Program Dokter Spesialis di bagian THT RS. Wahidin Sudirohusodo.

Publikasi pada jurnal ilmiah di dalam negeri

Penanggung jawab peneliti

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Lampiran 2. Data Dasar Hasil Penelitian

NO	NO.LAB	NAMA	JENIS KELAMIN	TGL.LAHIR	UMUR	PENDIDIKAN TERAKHIR	Suku	PEKERJAAN	VITAMIN D 25-OH TOTAL	KETERANGAN	GEJALA
1	2011150083	Tn. S	Laki-laki	11-May-1965	55	SMA	bugis	Mandor	21.1	asimtomatis	
2	2011150087	Tn. I	Laki-laki	5-Oct-1987	39	S1	bugis	Instalator listrik	20.7	asimtomatis	
3	2011150088	Tn.B	Laki-laki	4-Jan-1960	60	S1	Bugis	Pensiunan PNS	26.4	asimtomatis	
4	2011150090	Tn.Y	Laki-laki	1-Jul-1960	60	SD	Jawa	Tani	22.8	asimtomatis	
5	2011150093	Tn.A	Laki-laki	23-Oct-1975	45	S2	Jawa	PNS	24.0	asimtomatis	
6	2011210191	Ny. N	Perempuan	18-Apr-1981	39	S1	Bugis	Swasta	24.9	asimtomatis	
7	2011210195	Tn.L	Laki-laki	3-Aug-1976	44	SMA	Bugis	TNI	29.1	asimtomatis	
8	2011210198	Ny.S	Perempuan	16-Jul-1975	45	S1	Bugis	Swasta	20.9	asimtomatis	
9	2011210201	Tn..T	Laki-laki	11-Jun-2001	19	SMA	Bugis	Mahasiswa	24.0	asimtomatis	
10	2011210204	Tn.S	Laki-laki	3-Apr-1999	21	SMA	Bugis	TNI	36.7	asimtomatis	
11	2011210206	Tn..AB	Laki-laki	24-Nov-2002	18	SMA	Bugis	TNI	31.5	asimtomatis	
12	2011250112	Tn.AA	Laki-laki	30-Dec-1975	35	S1	Bugis	Swasta	21.6	asimtomatis	

13	2011250136	Tn.R	Laki-laki	15-May-1984	36	S1	Bugis	PNS	24.4	Asimtomatis	
14	2011250137	Tn.Z	Laki-laki	24-Jan-1981	39	S2	Bugis	Karyawan Swasta	27.6	asimtomatis	
15	2011250152	Ny.M	Perempuan	6-Oct-1993	27	D3	Bugis	Perawat	21.6	asimtomatis	
16	2011300189	Tn.R	Laki-laki	15-Sep-1983	37	SMA	Bugis	TNI	26.2	Asimtomatis	
17	2011300197	Tn.S	Laki-laki	11-Jun-1969	51	SMA	bugis	TNI	23.9	asimtomatis	
18	2011300200	Tn.A	Laki-laki	27-Jan-1968	52	SMA	Bugis	TNI	33.9	asimtomatis	
19	2011300208	Tn.E	Laki-laki	10-Jul-1962	58	SMA	Bugis	TNI	32.4	asimtomatis	
20	2011300211	Tn.EE	Laki-laki	30-Nov-1977	43	S1	Bugis	TNI/Perawat	20.6	asimtomatis	
21	2011300213	Tn.AM	Laki-laki	10-Feb-1977	43	S1	Bugis	PNS	23.8	asimtomatis	
22	2011300216	Ny.SD	Perempuan	30-Nov-1971	49	SMA	Bugis	IRT	25.5	asimtomatis	
23	2011150063	Ny.MU	Perempuan	10-Dec-1970	50	S1	bugis	Perawat/ PNS	15.2	simtomatis	Sedang
24	2011150085	Ny.F	Perempuan	26-Aug-1993	27	S1	bugis	Pns/ guru	13.2	simtomatis	Ringan
25	2011150091	Tn.SS	Laki-laki	17-Jul-1997	23	SMA	Bugis	penjaga Warnet	17.7	simtomatis	Ringan

26	2011150094	Tn.RA	Laki-laki	7-Jul-2001	19	SMA	Bugis	Bengkel	15.4	simtomatis	Ringan
27	2011210193	Ny.SMS	Perempuan	23-Mar-1975	45	S1	Bugis	PNS	14.4	simtomatis	Berat
28	2011210194	Ny.PN	Perempuan	3-Feb-2000	20	SMP	Bugis	ART	9.9	simtomatis	Sedang
29	2011210207	Ny.RF	Perempuan	28-Dec-1999	21	S1	Bugis	Swasta	11.3	simtomatis	Ringan
30	2011250118	Tn.MF	Laki-laki	28-May-1997	23	D4	Bugis	Staff Lab	14.0	simtomatis	Ringan
31	2011250122	Ny.RS	Perempuan	17-Nov-1985	35	S2	Bugis	PNS	19.5	simtomatis	Ringan
32	2011250123	Ny.DM	Perempuan	19-Sep-1972	48	S1	Bugis	PNS	20.1	simtomatis	Sedang
33	2011250127	Tn.MM	Laki-laki	25-Nov-1960	60	S1	Ambon	Swasta	25.8	simtomatis	Ringan
34	2011250132	Tn.SB	Laki-laki	14-Sep-1973	47	SMA	Bugis	Polri	19.4	simtomatis	Ringan
35	2011250141	Tn.MI	Laki-laki	7-Jan-1997	23	D3	Jawa	PNS	18.2	simtomatis	Ringan
36	2011250142	Ny.HK	Perempuan	26-Aug-1994	26	D3	Bugis	Swasta	10.1	simtomatis	Sedang
37	2011250146	Tn.MF	Laki-laki	28-Nov-1999	21	SMA	Ambon	Mahasiswa	19.5	simtomatis	Ringan
38	2011250150	Ny.NU	Perempuan	12-Jul-1966	54	SMA	Bugis	PNS TNI	19.1	simtomatis	Ringan

39	2011300196	Tn.MY	Laki-laki	10-Oct-1968	52	SMA	Bugis	Tani	26.0	simtomatis	Ringan
40	2011300199	Ny.RR	Perempuan	17-May-1976	44	S1	Bugis	IRT	14.9	simtomatis	Ringan
41	2011300202	Tn.I	Laki-laki	26-May-1982	37	S2	Bugis	Dosen/ PNS	10.0	simtomatis	Sedang
42	2011300205	Ny.SR	Perempuan	24-Aug-1962	58	SMA	Bugis	IRT	10.7	simtomatis	Ringan

Lampiran 3. Rekomendasi Persetujuan Etik



KEMENTERIAN PENDIDIKAN DAN KEBUDAYAAN
 UNIVERSITAS HASANUDDIN FAKULTAS KEDOKTERAN
 KOMITE ETIK PENELITIAN KESEHATAN
 RSPTN UNIVERSITAS HASANUDDIN
 RSUP Dr. WAHIDIN SUDIROHUSODO MAKASSAR
 Sekretariat : Lantai 2 Gedung Laboratorium Terpadu
 JL.PERINTIS KEMERDEKAAN KAMPUS TAMALANREA KM.10 MAKASSAR 90245.



Contact Person: dr. Agussalim Bukhari, MMed, PhD, SpGK TELP. 081241850858, 0411 5780103, Fax : 0411-581431

REKOMENDASI PERSETUJUAN ETIK

Nomor : 839/UN4.6.4.5.31/ PP36/ 2020

Tanggal: 30 Desember 2020

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

No Protokol	UH20110645	No Sponsor Protokol	
Peneliti Utama	dr. Indra Irawan	Sponsor	
Judul Peneliti	Perbandingan Kadar Vitamin D pada Pasien COVID-19 Konfirmasi asimtomasis dengan pasien COVID-19 konfirmasi simtomasis di Makassar		
No Versi Protokol	2	Tanggal Versi	30 Desember 2020
No Versi PSP	2	Tanggal Versi	30 Desember 2020
Tempat Penelitian	RS Universitas Hasanuddin dan RSUP Dr. Wahidin Sudirohusodo Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal	Masa Berlaku 30 Desember 2020 sampai 30 Desember 2021	Frekuensi review lanjutan
Ketua Komisi Etik Penelitian Kesehatan FKUH	Nama Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K)	Tanda tangan 	
Sekretaris Komisi Etik Penelitian Kesehatan FKUH	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 prokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan

Lampiran 4. Dokumentasi Penelitian





**KEMENTERIAN RISET, TEKNOLOGI, DAN PENDIDIKAN TINGGI
INDONESIA**

**UNIVERSITAS HASANUDDIN FAKULTAS
KEDOKTERAN
KOMITE ETIK PENELITIAN KESEHATAN**

Sekretariat : Lantai 3 Gedung Laboratorium Terpadu

JL.PERINTIS KEMERDEKAAN KAMPUS TAMALANREA KM.10, Makassar. Telp.0411-5044671, Fax
(0411) 586297.

Contact person dr.Agussalim Bukhari,M.Med.Ph.D,Sp.GK (HP. 081241850858), email: agussalimbukhari@ yahoo.com.

Lampiran 5 :

FORMULIR PERSETUJUAN SETELAH PENJELASAN

Yang bertanda tangan dibawah ini :

Nama :
Umur :
Jenis Kelamin :
Alamat :
Pekerjaan :

Setelah mendapatkan penjelasan dari peneliti dengan ini saya menyatakan bersedia secara sukarela tanpa paksaan untuk mengikuti penelitian ini dan mentaati semua prosedur yang akan dilakukan pada penelitian ini.

Saya tahu bahwa saya berhak untuk bertanya apabila masih ada hal-hal yang saya tidak mengerti.

Saya mengerti bahwa prosedur pemeriksaan kadar Vitamin D (Pengambilan darah dari vena cubiti) terhadap diri saya dapat menyebabkan hal-hal yang merugikan, namun saya percaya bahwa akan dilakukan tindakan-tindakan kewaspadaan untuk mencegah hal-hal tersebut. Resiko yang mungkin terjadi saat dilakukan pemeriksaan kadar vitamin D (pengambilan darah dari vena cubiti) adalah, rasa nyeri, perdarahan dilokasi pengambilan sampel, pembengkakan serta rasa tidak nyaman. Resiko ini kami antisipasi dengan memastikan lokasi vena cubiti, pencahayaan ruangan yang baik, pemberian plester luka pada daerah pengambilan sampel Serta melakukan pengambilan sampel pemeriksaan dengan tehnik yang benar.

Saya tahu bahwa saya berhak mendapat penanganan atau kompensasi biaya dari peneliti bila terjadi efek samping dari pemeriksaan yang dilakukan.

Saya juga berhak menolak untuk tidak ikut dalam penelitian ini tanpa kehilangan hak saya untuk mendapat pelayanan kesehatan dari dokter.

Makassar,

Nama Saksi

1. (.....)
Nama jelas/Tanda tangan

2. (.....)
(.....)
Nama jelas/Tanda tangan
tangan

Nama jelas/Tanda

Peneliti Utama : **dr. Indra Irawan**

Jl. mawar, Kompleks nusa Tamalanrea Indah, blok FD, nomor 07, Makassar

Telepon: 081348342555

Dokter Penanggung jawab medis : **Prof. Dr.dr. Eka Savitri, Sp.T.H.T.K.L(K)**

Jalan Hertasning VII nomor 22, Makassar.

Telepon : 081318494799

Lampiran 6 :

CASE REPORT FORM

Identitas Penderita

Nama :
Jenis kelamin/Umur : L/P
Agama :
Suku :
Pendidikan :
Pekerjaan :
Alamat :

Anamnesis

Gejala pada Penderita : Apakah anda mengalami keluhan berupa?

1. Apakah ada menderita Demam/ riwayat demam ($\geq 38^{\circ}\text{C}$) ?
2. Apakah ada batuk?
3. Apakah ada Pilek?
4. Apakah gampang merasa kelelahan saat beraktifitas?
5. Apakah ada sakit kepala?
6. Apakah ada nyeri otot?
7. Apakah ada nyeri tenggorok?
8. Apakah ada hidung tersumbat?
9. Apakah ada sesak napas?
10. Apakah ada mual/muntah?
11. Apakah ada penurunan napsu makan?
12. Apakah ada diare?
13. Apakah ada gangguan penghidu?
14. Apakah ada gangguan pengecap?
15. Apakah menderita penyakit diabetes mellitus dan hipertensi?
16. Apakah ada riwayat merokok?
17. Apakah ada riwayat cuci darah?
18. Apakah dalam pengobatan kortikosteroid, fenobarbital dan fenotoin?
19. Apakah ada riwayat pengobatan penyakit lainnya?
20. Apakah ada konsumsi Vitamin D sebelumnya?

Pemeriksaan Fisis Umum

Keadaan Umum

Tekanan Darah : Suhu :

Denyut nadi :

Pernapasan :

Pemeriksaan Tambahan:

CT Scan : ada/tidak ada

Hasil :

Foto Thoraks : ada / tidak ada

Hasil :

Pemeriksaan lainnya :

Diagnosa :

Catatan