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Lampiran 1

NASKAH PENJELASAN UNTUK MENDAPAT PERSETUJUAN DARI KELUARGA/SUBYEK PENELITIAN

Pengaruh Pemakaian nCPAP Terhadap Kadar Kortisol Saliva pada Bayi Cukup Bulan

Gangguan pernapasan pada saat kelahiran merupakan komplikasi signifikan yang terjadi pada bayi baru lahir, baik yang cukup bulan, kurang bulan, maupun lebih bulan. Bayi baru lahir dengan gangguan pernapasan pada umumnya dirawat di unit perawatan intensif neonatal (NICU) dan mengalami banyak prosedur yang menyebabkan stres dan nyeri. *Nasal continuous positive airway pressure* (nCPAP) merupakan standar perawatan untuk tatalaksana segera dan dukungan lanjutan pada bayi baru lahir, namun sayangnya tindakan ini berpotensi menimbulkan nyeri pada bayi. Nyeri yang tidak diobati selama periode kritis perkembangan otak ini dapat menyebabkan konsekuensi langsung dan jangka panjang pada bayi. Kortisol saliva merupakan salah satu penanda objektif terjadinya perubahan aksis *hypothalamic-pituitary-adrenal* (HPA) yang disebabkan oleh paparan berulang dan jangka panjang dari nyeri. Pengukuran kortisol saliva mudah dilakukan, tidak menimbulkan rasa

nyeri, dan merupakan tindakan non-invasif sehingga relatif lebih aman dilakukan.

Kami bermaksud mengadakan penelitian untuk mempelajari pengaruh pemasangan nCPAP terhadap kadar kortisol saliva. Kami menjamin bahwa penelitian ini tidak menimbulkan efek samping terhadap anak/kemanakan bapak/ibu, bahkan diharapkan hasil penelitian ini akan bermanfaat untuk penanganan nyeri yang ditimbulkan nCPAP dan juga membantu petugas medis dalam rangka mengambil keputusan yang tepat terhadap kondisi bayi. Bila ibu/bapak setuju untuk berpartisipasi diharapkan ibu/bapak dapat memberikan persetujuan secara tertulis.

Kami akan menanyakan dan mencatat identitas anak/kemanakan ibu/bapak (nama, alamat, tanggal lahir, jenis kelamin). Selanjutnya akan dilakukan pemeriksaan meliputi pengukuran berat badan dan tinggi badan, pemeriksaan tekanan darah, nadi, pernapasan dan suhu badan. Pemeriksaan fisik secara keseluruhan akan dilakukan. Kami akan melakukan pemeriksaan kadar kortisol saliva. Pemeriksaan ini tanpa dipungut biaya.

Keikutsertaan anak/kemanakan ibu/bapak dalam penelitian ini bersifat suka rela tanpa paksaan, karena itu ibu/bapak bisa menolak ikut atau berhenti ikut dalam penelitian ini tanpa takut akan kehilangan hak untuk mendapat pelayanan kesehatan yang dibutuhkan oleh anak/kemanakan ibu/bapak.

Semua data dari penelitian ini akan dicatat dan dipublikasikan tanpa membuka data pribadi anak/kemanakan ibu/bapak. Data pada penelitian ini akan dikumpulkan dan disimpan dalam file manual maupun elektronik, diaudit dan diproses serta dipresentasikan pada:

- Forum ilmiah Program Pasca Sarjana (S2) Universitas Hasanuddin
- Publikasi pada jurnal Ilmiah dalam negeri/ luar negeri

Setelah membaca dan mengerti atas penjelasan yang kami berikan mengenai pentingnya pemeriksaan kadar kortisol saliva, kami harapkan untuk menandatangani surat persetujuan mengikuti penelitian. Atas kesediaan dan kerjasamanya saya mengucapkan banyak terima kasih.

Tanda tangan / identitas peneliti:

Nama : dr. Noor Fadli Idrus

Alamat : Bontoduri Raya No. 22 Makassar

Telepon : 081340297310



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.,MIMed,PhD, SpGK TELP. 081241850858, 0411 5780103, Fax : 0411-581431

Lampiran 2

FORMULIR PERSETUJUAN MENGIKUTI PENELITIAN

Setelah mendengar, mengikuti dan menyadari pentingnya penelitian:
Pengaruh Pemakaian Ncpap Terhadap Kadar Kortisol Saliva Pada Bayi Cukup Bulan

Maka saya yang bertanda tangan di bawah ini :

Nama :

Umur :

Alamat :

Dengan ini menyatakan secara sukarela tanpa paksaan setuju untuk mengikutsertakan anak saya dalam penelitian ini:

Nama :

Umur :

Demikian surat persetujuan ini dibuat dengan sebenarnya untuk digunakan sebagaimana mestinya.

Makassar, 2020

Penanggung jawab

Orangtua

(dr. Noor Fadli Idrus)

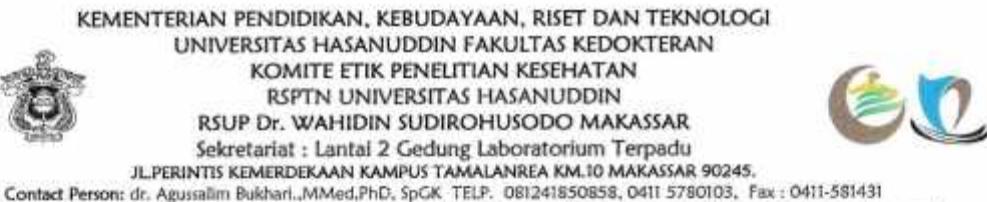
(.....)

Departemen Ilmu Kesehatan Anak FK-UNHAS

RS. Dr. Wahidin Sudirohusodo, Makassar

Telp.085213397465

Lampiran 3. Rekomendasi Persetujuan Etik



REKOMENDASI PERSETUJUAN ETIK

Nomor : 708/UN4.6.4.5.31/ PP36/ 2021

Tanggal: 8 Nopember 2021

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

No Protokol	UH21100622	No Sponsor Protokol	
Peneliti Utama	dr. A. Dwi Bahagia Febriani,PhD,SpA(K)	Sponsor	
Judul Peneliti	Pengaruh Pemakaian Bubble Nasal Continous Positive Airway Pressure (NCPAP) terhadap kadar kortisol saliva pada bayi baru lahir		
No Versi Protokol	2	Tanggal Versi	4 Nopember 2021
No Versi PSP	2	Tanggal Versi	4 Nopember 2021
Tempat Penelitian	RS Dr. Wahidin Sudirohusodo Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input checked="" type="checkbox"/> Fullboard Tanggal 21 Oktober 2021	Masa Berlaku 8 Nopember 2021 sampai 8 Nopember 2022	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 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

Diagnosa Anak	Diagnosa Ibu	Score EMA	Posisi	Cara Lahir	Luaran	Kortisol Sebelum	Kortisol Setelah	HB	Leukosit	trombosit	prokal	CRP
RDN + Curiga besar sepsis + BCB/SMK	Inpartu	2	Terlentang	normal	Pulang	1.55	20.08	13.7	13,000	287,000		43
RDN ec TTN	Plasenta Previa	2	Terlentang	SC	Pulang	2.7	20.6	13.5	12,600	314,000		
RDN + curiga besar sepsis + BCB/SMK	Post SC	2	Miring	SC	Pulang	2.9	19.76	15.5	10,000	151,000		14.1
RDN	Ketuban Pecah Dini	2	Terlentang	SC	Pulang	2.4	2.8	16.2	19,700	279,000		
RDN + Curiga besar sepsis	Kala 2 lama	1	Terlentang	SC	Pulang	9.7	13.7	12.3	11,100	696,000		
RDN	Plasenta Akreta	1	Miring	SC	Pulang	35.2	35.7					
RDN + curiga besar sepsis	Plasenta Previa	1	Miring	SC	Pulang	66.5	92	11.1	5000	180,000		
RDN	Post SC	1	Terlentang	SC	Pulang	0.4	2.1	12.2	8000	150,000		
RDN	Post SC	2	Terlentang	SC	Pulang	0.7	9.1	15.4	10,400	259,000		
RDN ec TTN	Plasenta Previa	2	Terlentang	SC	Pulang	1.6	13.4	12.4	16,200	335,000		
RDN	Post SC	1	Terlentang	SC	Pulang	4.1	19.4	15.1	14,700	201,000		
RDN + Curiga sepsis	Inpartu	1	Terlentang	Normal	Pulang	0.6	3.1					
RDN	PEB	1	Terlentang	Normal	Pulang	2.8	46	13.3	11,900	529,000		
RDN + Curiga besar sepsis	Ketuban Pecah Dini	2	Terlentang	Normal	Pulang	2.6	16	13.4	10,000	345,000		
RDN ec TTN	Post SC	1	Terlentang	SC	Pulang	0.4	1.8					
RDN	PEB	2	Miring	Normal	Perawatan	0.8	24	12.2	9500	323,000		
RDN	PEB	2	Miring	SC	Perawatan	2.1	2.2					
RDN + Curiga besar sepsis	Ketuban Pecah Dini	2	Terlentang	SC	Pulang	0.3	33	17.1	4,400	172,000		
RDN ec TTN	Post SC	2	Miring	sc	Pulang	0.1	2.5	13.9	22,390	273,000		
RDN + Curiga besar sepsis + BCB/SMK	Ketuban Pecah Dini	2	Terlentang	normal	Pulang	6.9	7.1					
RDN	Post SC	2	Terlentang	sc	Pulang	2.4	2.5					
RDN	Plasenta Akreta	0	Miring	SC	Perawatan	0.8	1	11.1	10,900	326,000		
RDN ec TTN	Post SC	1	Miring	SC	Perawatan	1.7	3.9	17.2	22,300	172,000		
RDN	Inpartu	0	Terlentang	Normal	Perawatan	0.4	0.8					
RDN	Superimpose Preeklampsia	1	Miring	SC	Pulang	0.1	3.6	15.2	10,000	189,000	0.46	12
RDN	Preeklampsia Berat]1	Miring	SC	Pulang	0.7	1.8					
RDN	Preeklampsia Berat	2	Terlentang	SC	Pulang	12	29					
RDN	Ketuban Pecah Dini	1	Miring	SC	pulang	47	51					
RDN	Post SC	1	Miring	SC	Pulang	0.2	19					
RDN	KALA 2 lama	2	Terlentang	SC	Pulang	14	25					
RDN ec TTN	Post SC	1	Terlentang	SC	Meninggal	0.3	1.9					
RDN	Plasenta Previa	1	Miring	SC	Perawatan	2.4	6.5					
RDN + Curiga besar sepsis	KPD	1	Miring	SC	Pulang	1	2.5					
RDN	kala 2 lama	1	Miring	SC	Perawatan	0.1	0.4					
RDN	Inpartu	1	Miring	normal	Pulang	0.2	12.4					
RDN + Curiga besar sepsis	Ketuban Pecah Dini	1	Terlentang	Normal	Perawatan	0.7	1					
RDN ec TTN	Post SC	1	Miring	SC	Pulang	3.7	3.9	14.3	15,200	150,000		
RDN	Post SC	1	Miring	SC	Pulang	2.1	3					