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Lampiran 1

NASKAH PENJELASAN UNTUK RESPONDEN (SUBYEK)

Assalamualaikum wr. wb. Salam Ibu, saya dr. M. Mirza Aditya Hakim, asisten OBGIN yang akan melakukan penelitian mengenai **Perbandingan Kadar Hormon Relaksin dan Kekuatan Otot Dasar Panggul pada Perempuan Menopause dengan Inkontinensia Urin Tipe Stress dengan yang Tidak Inkontinensia Urin**. Penelitian ini bertujuan Mengetahui perbandingan dar hormon relaksin pada pasien dengan inkontinesia urin tipe stress dengan yang tidak inkontinnsia urin. Untuk itu kami memerlukan; data Ibu seperti yang tertera pada kuisisioner, serta mengambil sampel darah Ibu untuk kami periksakan di laboratorium. Hasil penelitian ini akan disajikan pada Forum Ilmiah Program Pendidikan Dokter Spesialis-I Obstetri dan Ginekologi Fakultas Kedokteran Universitas Hasanuddin Makassar.

Semua biaya yang ditimbulkan oleh penelitian ini sepenuhnya ditanggung oleh peneliti. Perlu ibu ketahui bahwa ibu mempunyai hak untuk menolak ikut dalam penelitian ini. Demikian pula bila terjadi hal-hal yang tidak memungkinkan ibu untuk terus ikut dalam penelitian ini maka ibu berhak mengundurkan diri. Penolakan ibu tidak mempengaruhi tindakan atau pengobatan yang seharusnya dilakukan pada ibu, tetapi kesediaan ibu akan memberi manfaat yang besar. Kami akan sangat menghargai keikutsertaan ibu terhadap pengembangan ilmu kedokteran ini.

Kami menjamin keamanan dan kerahasiaan semua data pada penelitian ini. Data penelitian ini akan dikumpulkan dan disimpan tanpa menyebutkan nama ibu dalam arsip tertulis atau elektronik yang tidak bisa dilihat oleh orang lain selain tim peneliti. Kami akan kembali meminta izin menggunakan data ibu secara anonim apabila diperlukan dikemudian hari.

Apabila Ibu merasa masih ada hal yang belum jelas atau belum dipahami dengan baik, maka Ibu dapat meminta penjelasan lebih lanjut pada saya : dr. M. Mirza Aditya Hakim (Telp. 081354295031).

Apabila ibu bersedia berpartisipasi, silakan menandatangani surat persetujuan mengikuti penelitian. Atas kesedian ibu meluangkan waktu untuk mengikuti penjelasan ini, kami mengucapkan terima kasih.

IDENTITAS PENELITI

Nama : dr. M. Mirza Aditya Hakim

Alamat : Jl. Faisal V No. 20B

Telepon : 081354295031

Email : mirzaichot@gmail.com

Lampiran 2

**FORMULIR PERSETUJUAN MENGIKUTI PENELITIAN
SETELAH MENDAPAT PENJELASAN**

Saya yang bertanda tangan dibawah ini :

Nama :

Umur :

Alamat :

Pekerjaan :

No. Telepon :

Dengan ini menyatakan bahwa setelah saya mendapatkan penjelasan serta memahami sepenuhnya maksud dan tujuan penelitian yang berjudul :

**PERBANDINGAN KADAR HORMON RELAKSIN DAN KEKUATAN
OTOT DASAR PANGGUL PADA PEREMPUAN MENOPAUSE DENGAN
INKONTINENSIA URIN TIPE STRES DAN TANPA INKONTINENSIA
URIN TIPE STRES**

Maka saya menyatakan **SETUJU** untuk ikut serta dalam penelitian ini, mematuhi semua ketentuan yang berlaku dan memberikan keterangan yang sebenarnya.

Demikian pernyataan ini saya buat untuk digunakan sebagaimana mestinya.

	NAMA	TANDA TANGAN	TANGGAL
Pasien
Saksi 1
Saksi 2

IDENTITAS PENELITIAN

Nama : dr. M. Mirza Aditya Hakim

Alamat : Jl. Faisal V No. 20B

Telepon : 081354295031

PENANGGUNG JAWAB MEDIK

Nama : Dr. dr. Trika Irianta, Sp.OG(K)

Alamat : Jl. Hati Murah No.30

Telepon : 08124225531

Lampiran 3

Etikal Kliens



KEMENTERIAN PENDIDIKAN DAN KEBUDAYAAN
UNIVERSITAS HASANUDDIN FAKULTAS KEDOKTERAN
KOMITE ETIK PENELITIAN KESEHATAN
RSPIN 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. Agusdim Bukhari, MMed,PhD, Sp.GA, Telp. 08124050058, 0411 570003, Fax : 0411 501431

REKOMENDASI PERSETUJUAN ETIK

Nomor : 600/UN4.6.4.5.31/PP36/2020

Tanggal: 29 September 2020

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

No Protokol	UH20090475	No Sponsor Protokol	
Peneliti Utama	dr. M. Mirza Aditya Hakim	Sponsor	
Judul Peneliti	Perbandingan Kadar Hormon Relaksin dan Otot Dasar Panggul Pada Perempuan Menopause Dengan Inkontinensia Urin Tipe Stres dan Tanpa Inkontinensia Urin Tipe Stres		
No Versi Protokol	1	Tanggal Versi	10 September 2020
No Versi PSP	1	Tanggal Versi	10 September 2020
Tempat Penelitian	RSUP Dr.Wahidin Sudirohusodo dan RS Jejaring di Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal	Masa Berlaku 29 September 2020 sampai 29 September 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 protokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan

Lampiran 4**KUISIONER PENELITIAN****I. IDENTITAS PASIEN**

Nama :
Tanggal lahir :
Alamat lengkap :
Nomor telepon :
Agama : Islam / Kristen / Katolik / Budha / Hindu
Pendidikan terakhir : Tidak sekolah / SD / SMP / SMA / PT
Pekerjaan :
Umur : tahun
Berat badan : Kg
Tinggi badan : cm
IMT :
Status nutrisi :
Riwayat penyakit kandungan : Histerektomi / Radiasi / Prolaps organ
panggul
Riwayat penyakit terdahulu : Stroke / trauma tulang belakang /
Kelainan saraf / Diabetes / Batuk
kronis
Menopause sejak :

Riwayat Kontrasepsi	: Tidak pernah / Kondom / Pil / Suntik / Implan / IUD / Sterilisasi / Terapi hormon
Status perkawinan	: Tidak Kawin / Kawin
Lama perkawinan	:
Riwayat persalinan	: Abortus kali / Pervaginam kali / Pervaginam berbantu kali / Sectio sesaria kali

Questionnaire for Urinary Incontinence Diagnosis (QUID)

Apakah ada urin yang keluar (walaupun setetes), membasahi diri anda, atau membasahi pembalut atau pakaian dalam anda:

1. Ketika anda batuk atau bersin

- Tidak pernah.....(0)
- Jarang.....(1)
- Sesekali.....(2)
- Sering.....(3)
- Biasa.....(4)
- Setiap waktu.....(5)

2. Ketika anda membungkuk atau mengangkat sesuatu

- Tidak pernah.....(0)
- Jarang.....(1)
- Sesekali.....(2)
- Sering.....(3)

- Biasa.....(4)
- Setiap waktu.....(5)
3. Ketika anda berjalan cepat, berlari atau olahraga
- Tidak pernah.....(0)
- Jarang.....(1)
- Sesekali.....(2)
- Sering.....(3)
- Biasa.....(4)
- Setiap waktu.....(5)
4. Ketika anda membuka pakaian saat di toilet
- Tidak pernah.....(0)
- Jarang.....(1)
- Sesekali.....(2)
- Sering.....(3)
- Biasa.....(4)
- Setiap waktu.....(5)
5. Apakah anda mengalami rasa tidak nyaman dan keinginan yang kuat sehingga ada urin yang keluar (walaupun setetes) atau membasahi diri anda sebelum sampai di toilet
- Tidak pernah.....(0)
- Jarang.....(1)
- Sesekali.....(2)
- Sering.....(3)

Biasa.....(4)

Setiap waktu.....(5)

6. Apakah anda bergegas ke toilet secara karena ada dorongan untuk buang air kecil secara tiba-tiba

Tidak pernah.....(0)

Jarang.....(1)

Sesekali.....(2)

Sering.....(3)

Biasa.....(4)

Setiap waktu.....(5)

Inkontinensia urin tipe stres: No. 1,2 dan 3 jumlahnya >4

Inkontinensia urin tipe urgensi: No. 4,5 dan 6 jumlahnya >6

Inkontinensia urin tipe campuran: Gabungan antara kedua tipe diatas

Diagnosis akhir :

Kadar Relaksin :

Kekuatan otot dasar panggul :

Lampiran 6 Data Penelitian

No.	Umur (tahun)	Pendidikan	Pekerjaan	IMT (kg/m ²)	Status gizi	Lama menopause (tahun)	Kontrasepsi	Persalinan	Relaksin (ng/ml)	Kekuatan otot (mmH ₂ o)	IU
1	60	Dasar	Bekerja	19.53	normal	10	Tidak menggunakan	Multipara	825	15.93	1
2	47	Menengah	IRT	20.20	normal	5	Tidak menggunakan	Multipara	626	29.07	1
3	54	Dasar	IRT	24.39	Overweight	2	Tidak menggunakan	Multipara	740	18.37	1
4	57	Dasar	IRT	27.39	Obesitas	5	hormonal	Multipara	788	48.17	1
5	69	Dasar	IRT	20.45	Normal	15	Tidak menggunakan	Grand Multipara	545	62.00	1
6	53	PT	Bekerja	28.00	Obesitas	2	hormonal dan non hormonal	Multipara	641	12.53	1
7	55	Dasar	IRT	24.44	normal	6	hormonal	Multipara	633	24.37	1
8	55	PT	Bekerja	24.97	normal	14	Tidak menggunakan	Primipara	730	20.60	1
9	52	Menengah	IRT	20.81	Normal	3	hormonal	Grand Multipara	525	27.50	1
10	55	Menengah	Bekerja	24.75	Overweight	10	hormonal	Multipara	601	10.93	1
11	57	Menengah	IRT	20.89	Normal	2	hormonal	Multipara	523	17.10	1
12	55	Dasar	IRT	22.83	Normal	7	hormonal	Grand Multipara	524	22.73	1
13	53	Menengah	IRT	23.23	normal	3	Tidak menggunakan	Multipara	722	23.07	1
14	51	PT	Bekerja	32.89	Obesitas	3	hormonal	Multipara	666	24.33	1
15	55	PT	Bekerja	23.23	normal	5	hormonal dan non hormonal	Grand Multipara	589	43.13	1
16	62	Dasar	IRT	23.44	normal	12	Tidak menggunakan	Grand Multipara	516	22.33	1
17	53	Menengah	IRT	31.96	Obesitas	2	hormonal	Multipara	626	17.37	1
18	53	Menengah	IRT	24.14	overweight	4	Tidak menggunakan	Multipara	703	19.00	1
19	50	Menengah	IRT	24.38	Normal	1	Tidak menggunakan	Multipara	704	23.00	1
20	73	Menengah	IRT	24.15	Overweight	22	Tidak menggunakan	Multipara	849	20.00	1
21	61	Dasar	Bekerja	20.28	Normal	10	Tidak menggunakan	Multipara	694	23.00	1

22	57	PT	Bekerja	24.96	Overweight	5	hormonal	Multipara	685	18.00	1
23	52	Dasar	IRT	24.22	Normal	2	Non hormonal	Multipara	686	18.00	1
24	55	Dasar	IRT	24.22	Normal	4	Tidak menggunakan	Multipara	769	21.00	1
25	81	Dasar	IRT	20.81	normal	25	Tidak menggunakan	Multipara	789	23.00	1
1	63	Dasar	IRT	20.20	normal	15	hormonal	Grand Multipara	558	5.90	2
2	50	Dasar	IRT	22.60	normal	2	Non hormonal	Multipara	468	11.37	2
3	53	Menengah	Bekerja	21.36	normal	7	Non hormonal	Multipara	436	14.97	2
4	69	Dasar	IRT	24.89	Overweight	15	Tidak menggunakan	Grand Multipara	512	10.53	2
5	45	PT	Bekerja	24.78	Overweight	1	hormonal	Multipara	556	19.57	2
6	51	Menengah	Bekerja	22.27	normal	4	hormonal dan non hormonal	Multipara	521	13.17	2
7	52	Dasar	IRT	22.51	normal	5	hormonal	Multipara	494	36.23	2
8	65	Dasar	IRT	18.00	normal	15	hormonal	Multipara	223	4.20	2
9	54	Menengah	IRT	20.00	normal	1	hormonal	Multipara	486	6.50	2
10	50	Menengah	IRT	20.70	normal	1	Tidak menggunakan	Multipara	244	12.30	2
11	51	Dasar	IRT	24.97	Overweight	2	hormonal	Multipara	494	8.63	2
12	54	Menengah	IRT	24.22	Overweight	4	hormonal dan non hormonal	Multipara	499	14.27	2
13	52	Dasar	IRT	24.14	Overweight	5	hormonal	Grand Multipara	542	11.60	2
14	52	Dasar	IRT	19.83	normal	2	hormonal	Multipara	475	5.87	2
15	57	Dasar	IRT	24.00	Overweight	4	hormonal	Grand Multipara	325	14.37	2
16	52	Menengah	Bekerja	24.97	Overweight	6	Tidak menggunakan	Nulipara	559	10.43	2
17	56	Menengah	IRT	21.76	normal	4	hormonal dan non hormonal	Multipara	486	34.23	2
18	55	Dasar	IRT	24.62	Overweight	5	Non hormonal	Multipara	696	10.00	2
19	47	Dasar	IRT	22.89	normal	2	Non hormonal	Multipara	555	8.00	2
20	52	Dasar	IRT	19.48	normal	2	Tidak menggunakan	Multipara	590	18.00	2
21	72	Dasar	IRT	25.78	Obesitas	20	Tidak menggunakan	Multipara	720	18.00	2

22	66	Dasar	IRT	21.64	normal	15	hormonal	Multipara	421	7.00	2
23	56	Dasar	IRT	22.22	normal	6	Non hormonal	Multipara	555	17.00	2
24	56	Dasar	IRT	20.23	normal	6	hormonal	Multipara	702	14.00	2
25	51	Dasar	IRT	26.45	Obesitas	13	Tidak menggunakan	Multipara	634	13.00	2

Lampiran 7 Prosedur Penelitian





