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Lampiran 1

FORM INFORMED CONSENT

Penjelasan Penelitian untuk Disetujui (Information for consent)

Nama Peneliti : Najmiah N. Djakaria

Judul Penelitian:

PENGARUH PEMBERIAN PRAVASTATIN TERHADAP KADAR Nitrat OKSIDA
PADA PASIEN RISIKO TINGGI PREEKLAMPSIA

- A. Tujuan penelitian & penggunaan hasilnya
Penelitian ini bertujuan untuk menilai efektifitas obat (Pravastatin) dalam menurunkan kadar Nitrat oksida pada pasien risiko tinggi preeklamsia.
- B. Manfaat bagi peserta penelitian
Penemuan terapi baru untuk mencegah preeklamsia dengan menilai perubahan kadar Nitrat oksida pada ibu yang memiliki risiko tinggi terhadap preeklamsia

Metode dan prosedur kerja penelitian

- Penderita yang memenuhi kriteria inklusi dan eksklusi akan diberikan penjelasan mengenai penelitian ini, mulai tujuan penelitian, perlakuan, pengawasan, efek samping, risiko, pengambilan sampel dan lain-lain
- Penderita akan ditawarkan untuk ikut berpartisipasi dalam penelitian ini, dan dijelaskan hak dan kewajiban sebagai partisipan penelitian
- Jika penderita setuju menjadi partisipan penelitian ini, maka wajib menandatangani lembar persetujuan penelitian
- Partisipan kemudian akan dilakukan randomisasi menjadi dua kelompok: yang menerima kombinasi pravastatin dan aspirin, serta yang menerima aspirin saja
- Partisipan akan meminum obat sampai akhir kehamilan
- Kadar endotelin-1 akan diperiksa sebelum dan setelah pemberian obat.

C. Resiko yang mungkin timbul

Penelitian terkini menunjukkan bahwa pemberian pravastatin pada ibu hamil tidak meningkatkan risiko terjadinya kelainan bawaan pada janin.

1. Penelitian Data farmakologis Merck, dengan 477 ibu hamil yang mengkonsumsi statin. Tidak terbukti adanya peningkatan risiko kelainan bawaan pada janin pada ibu hamil yang mengkonsumsi simvastatin atau lovastatin (Kazmin A et al, 2007).
2. Dari penelitian metaanalisis berskala besar, yang menilai efek pemberian statin pada ibu hamil trimester pertama. Tidak didapatkan peningkatan risiko kelainan bawaan janin, namun didapatkan sedikit peningkatan risiko keguguran pada trimester pertama (Zarek J, Koren G, 2014).

D. Efek samping penelitian

Konsumsi pravastatin dapat menimbulkan efek samping ringan (nyeri ulu hati, nyeri otot, nyeri dada, pusing, diare, nyeri kepala, batuk, bengkak, mual muntah, demam, kelelahan, sesak ringan, gejala flu), dan risiko efek samping berat (gangguan liver, dan kelainan otot). Dari penelitian Constatine (2016), tidak didapatkan peningkatan risiko terjadinya efek samping pada pemberian pravastatin.

E. Tindak lanjut jika terjadi insiden saat dilaksanakan penelitian

Apabila terjadi insiden akan dilakukan tindakan pengobatan sesuai standar yang biayanya ditanggung oleh peneliti.

F. Jaminan kerahasiaan

Identitas peserta penelitian, data, hasil penelitian dan semua yang berhubungan dengan penelitian ini akan dirahasiakan oleh tim peneliti.

G. Hak untuk menolak menjadi subyek penelitian

Subyek penelitian berhak menolak ikut serta dalam penelitian tanpa mempengaruhi perawatan selanjutnya.

H. Partisipasi berdasarkan kesukarelaan dan hak untuk mengundurkan diri

Subyek penelitian berpartisipasi secara sukarela, diberi kesempatan untuk menanyakan hal-hal yang belum jelas dan berhak mendapatkan jawaban yang memuaskan. Tiap saat dalam periode penelitian, subyek penelitian berhak mengundurkan diri dari penelitian.

I. Subjek dapat dikeluarkan dari penelitian

Bila subyek penelitian tidak mentaati instruksi yang diberikan oleh para peneliti, maka dapat dikeluarkan setiap saat dari penelitian ini.

J. Penelitian ini dilakukan oleh

Makassar,

Yang memberi penjelasan

Yang menerima penjelasan

(.....)

(.....)

Saksi I

Saksi II

(.....)

(.....)

Lampiran 2

FORM INFORMED CONSENT

LEMBAR PERSETUJUAN MENGIKUTI PENELITIAN (Informed consent)

Saya yang bertanda tangan dibawah ini :

Nama
:.....
Umur
:.....
Alamat
:.....
Tlp / Email
:.....

Sesudah mendengarkan penjelasan yang diberikan dan diberikan kesempatan untuk menanyakan yang belum dimengerti, dengan ini memberikan :

PERSETUJUAN

Mengikuti penelitian sebagai subyek penelitian dengan judul penelitian:
PENGARUH PEMBERIAN PRAVASTATIN TERHADAP KADAR NITRAT
OKSIDA PADA PASIEN RISIKO TINGGI PREEKLAMPSIA
dan sewaktu-waktu saya berhak mengundurkan diri.
Demikian persetujuan ini saya buat dengan penuh kesadaran dan tanpa paksaan.

Makassar,

Yang memberi penjelasan

Yang membuat pernyataan

(.....)

(.....)

Saksi I

Saksi II

(.....)

(.....)

Lampiran 3

LEMBAR PERSETUJUAN TINDAKAN MEDIS

Saya yang bertanda tangan dibawah ini :

Nama

.....

Umur

.....

Alamat

.....

Tlp / Email

.....

Sesudah mendengarkan penjelasan yang diberikan dan diberikan kesempatan untuk menanyakan yang belum dimengerti, dengan ini memberikan :

PERSETUJUAN

Untuk dilakukan tindakan medis
berupa:

Dengan judul penelitian:

PENGARUH PEMBERIAN PRAVASTATIN TERHADAP KADAR NITRAT
OKSIDA PADA PASIEN RISIKO TINGGI PREEKLAMPSIA

Subjek penelitian juga menyetujui bahwa sampel yang diambil akan dapat dilakukan pemeriksaan di laboratorium baik di dalam atau luar negeri.

Sewaktu-waktu saya berhak mengundurkan diri.

Demikian persetujuan ini saya buat dengan penuh kesadaran dan tanpa paksaan.

Makassar,

Yang Membuat Pernyataan

(.....)

Saksi 1

Saksi 2

(.....)

(.....)

Lampiran 4

LEMBAR PENGUMPULAN DATA DASAR PESERTA PENELITIAN

Nama

:

Usia

:

No Rekam Medis

:

Rumah Sakit

:

Alamat

:

No Telp

:

Kelompok : Pravastatin - Kontrol

Data Fisik, Antropologis, dan Etnografis

Suku : Makassar-Bugis-Mandar-Toraja

Tempat kelahiran

:

Tempat kelahiran orang

tua :

Paritas :

Gravida

:

Tinggi badan : cm

Berat Badan : kg

BMI : kg/m²

Riwayat Penyakit

Hipertensi : + / -

Penyakit ginjal : + / -

Diabetes mellitus : + / - [jika +, Tipe 1 atau Tipe 2]

Penyakit vaskular kolagen (SLE, APS) : + / -

Riwayat Preeklamsia : + / -

Riwayat DM Gestasional : + / -

Riwayat Obsetri

(Berikan keterangan kehamilan keberapa dan usia kehamilan saat terjadinya)

Keguguran	:	+	/	-
.....				
Kematian janin dalam rahim	:	+	/	-
.....				
Keguguran yang diinduksi	:	+	/	-
.....				
Hipertensi Gestasional	:	+	/	-
.....				
Preeklamsia	:	+	/	-
.....				
Eklampsia	:	+	/	-
.....				
Sindroma HELLP	:	+	/	-
.....				
IUGR atau Bayi KMK	:	+	/	-
.....				
DM Gestasional memerlukan insulin	:	+	/	-
.....				
Persalinan preterm (< 37 minggu):		+	/	-
.....				
Kematian neonatal	:	+	/	-
.....				

Riwayat Kehamilan Saat Ini

Tekanan darah saat pertama datang
(booking) : mmHg

Kehamilan multipel	:	+ / -
Mola Hidatidosa	:	+ / -
Plasenta hidrofik	:	+ / -
Konsumsi obat anti hipertensi	:	+ / -
Mendapat terapi SM	:	+ / -
Mendapat terapi steroid untuk maturasi paru	:	+ / -
Mendapat terapi obat anti tiroid	:	+ / -

Hasil pemeriksaan

Kadar endothelin-1 sebelum terapi :
 Kadar endothelin-1 setelah terapi :
 Kadar profil lipid sebelum terapi :
 Kadar profil lipid setelah terapi :
 Kadar NO darah sebelum terapi :
 Kadar NO darah setelah terapi :
 RI doppler arteri uterina :
 Fetal scan pada uk 20 - 24 minggu :
 Doppler arteri umbilikalis :
 Biometri janin pada usia kehamilan 28 - 32 minggu :

Diagnosis Preeklamsia

Data tekanan darah tertinggi selama kehamilan :
 Data tekanan darah tertinggi saat persalinan :
 Data tekanan darah tertinggi 48 jam setelah persalinan :
 Proteinuria :
 +
 Keterlibatan multiorgan (trombositopenia, peningkatan SGOT/SGPT, BUN-SK, kejang, persalinan preterm, IUGR, kematian fetal atau neonatal): ya - tidak

Luaran Ibu

Mengalami Preeklamsia : + / -
 Mengalami Preeklamsia Berat : + / -
 Mengalami Hipertensi Gestasional : + / -
 Kematian Ibu : + / -

 Persalinan preterm < 37 minggu : + / -
 Persalinan preterm < 34 minggu : + / -
 Komplikasi Ibu : + / - [jika ya, sebutkan: edema paru, eklampsia, gagal ginjal akut, sindroma HELLP, tekanan darah \geq 180/110 mmHg, DIC, CVA]
 Lama Perawatan di RS : + / -
 Metode persalinan : Per vaginam - Pervaginam dengan alat - SC

Luaran Janin

Kematian fetal-neonatal : + / -
 Morbiditas neonatal gabungan (IUGR, RDS, ICH, NEC, neonatal sepsis, IUGR) : + / -
 Usia Kehamilan saat dilahirkan :
 Berat Badan Bayi : g
 Panjang Badan Bayi : cm
 Ballard Score (jika ada) : minggu
 Lutzchenko Score (jika ada) : P
 Kelainan kongenital : + / -
 Tingkat perawatan : Bayi sehat - intermediate care - NICU
 Lama perawatan di NICU : hari
 Pemakaian ventilator : + / -
 Lama perawatan di RS : hari
 Mengalami gangguan dalam rahim (oligohidramnion berat, AEDV atau REDV pada arteri umbilikalis, abnormal NST) : + / -

Efek Samping Obat

Nyeri kepala : + / -
 Insomnia : + / -
 Flushing skin : + / -
 Nyeri otot, atau kelemahan : + / -
 Mengantuk berlebihan : + / -
 Pusing : + / -
 Mual muntah : + / -
 Nyeri abdomen hebat : + / -
 Kembung : + / -
 Diare : + / -
 Konstipasi : + / -
 Bercak kulit : + / -

Efek Samping Berat Obat

Miositis (keradangan otot) : + / -
 Rhabdomyolisis : + / -

Catatan: Pemilihan jenis data dasar yang dikumpulkan berdasarkan pada standarisasi penelitian Preeklamsia yang dikeluarkan COLAB (Global Pregnancy CoLaboratory): Strategy for Standardization of Preeclampsia Research Study Design (Myatt L et al, 2014) dan luaran penelitian ini.

Lampiran 5

PROTOKOL PENELITIAN

1. Tim peneliti melakukan skrining pada semua ibu hamil usia kehamilan 12 minggu – 19 minggu 6 hari di poliklinik
2. Ibu hamil yang memenuhi kriteria inklusi dan eksklusi akan ditawarkan untuk terlibat dalam penelitian ini
3. Tim peneliti memberikan penjelasan (information for consent) secara detail mengenai tujuan penelitian, prosedur penelitian, perlakuan, monitoring dan follow up pasien, hak dan kewajiban partisipan penelitian.
4. Jika pasien bersedia mengikuti penelitian ini, maka harus menandatangani lembar persetujuan penelitian (informed consent)
5. Kemudian tim peneliti akan mengambil data dasar partisipan dari wawancara dan pemeriksaan fisik (sesuai lampiran 4)
6. Tim peneliti kemudian akan membagi partisipan kedalam kelompok perlakuan atau kontrol berdasarkan randomisasi yang telah ditetapkan sebelumnya, kemudian akan diambil sampel darah pasien.
7. Pembagian randomisasi kelompok dapat dilakukan sendiri oleh tim peneliti atau pihak farmasi rumah sakit
8. Setelah partisipan dimasukkan dalam salah satu kelompok, maka ia harus meminum obat tersebut selama kehamilan
9. Tim peneliti akan memfollow up dan memonitor partisipan selama kehamilan sesuai dengan jadwal pemeriksaan kehamilan standar
10. Adanya efek samping obat patut dievaluasi oleh tim peneliti, dan dicatat di lembar pengumpulan data (lampiran 4)
11. Partisipan akan diikuti sampai usia kehamilan 36 minggu, dan diambil sampel darah.
12. Tim peneliti akan mencatat luaran maternal dan fetal-neonatal setelah partisipan melahirkan sebagai luaran penelitian ini
13. Hasil luaran penelitian dan data dasar partisipan akan dicatat dan dikompilasi di lembar kompilasi hasil penelitian (dalam bentuk file microsoft excel)

Nama Tim Peneliti (No Telpon):

1. Dr. dr. Deviana Soraya Riu, SpOG (K)
2. dr. Ellen Wewengkang, SpOG
3. dr. Rizky A Ramadhani (082297669191)
4. dr. Andre Septian Putra (082266609863)

5. dr. Najmiah Nur Indah Djakaria (082190246304)
Lampiran 6 : Rekomendasi persetujuan Etik


KEMENTERIAN PENDIDIKAN DAN KEBUDAYAAN
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 Contact Person: dr. Agussalim Bukhari, M.Med.,Ph.D., Sp.GK. Telp. 081240850858, 0411 5780003. Fax : 0411-581431



REKOMENDASI PERSETUJUAN ETIK
 Nomor : 230/UN4.6.4.5.31/ PP36/ 2020

Tanggal: 10 Maret 2020

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

No Protokol	UH20010009		No Sponsor	
Peneliti Utama	dr. Najmiah Nur Indah Dj		Sponsor	
Judul Peneliti	Pengaruh Pemberian Pravastatin Terhadap Kadar Nitrat Oksida Pada pasien Risiko Tinggi Preeklamsia			
No Versi Protokol	2	Tanggal Versi	2	Maret 2020
No Versi PSP	2	Tanggal Versi	2	Maret 2020
Tempat Penelitian	Puskesmas Jumpangang Baru Makassar			
Jenis Review	<input type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input checked="" type="checkbox"/> Fullboard Tanggal 22 Januari 2020		Masa Berlaku 10 Maret 2020 sampai 10 Maret 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 ditengklapi 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 7 : Surat Izin Penelitian

 RUMAH SAKIT UNHAS FORMULIR 2 BIDANG PENELITIAN DAN INOVASI	SURAT IZIN PENELITIAN	
	Nomor: 2756/UN4.24.1.2/PT.01.04/2021	Tanggal 08 Maret 2021
	Kepada Yth Kepala Ruang Laboratorium Penelitian	
<p>Dengan hormat,</p> <p>Dengan ini menerangkan bahwa peneliti/ mahasiswa berikut ini:</p> <p>Nama : dr. Najmiah N Djakaria</p> <p>NIM / NIP : C055172010</p> <p>Institusi : Departemen Obstetri dan Ginekologi, Fakultas Kedokteran, Universitas Hasanuddin Makassar</p> <p>Kode penelitian : 210308_1</p> <p>Akan melakukan pengambilan data/ analisa bahan hayati:</p> <p>Terhitung : 08 Maret 2021 s/d 08 Juni 2021</p> <p>Jumlah Subjek/Sample : 76</p> <p>Jenis Data : Data Primer : Elisa</p> <p>Untuk penelitian dengan judul: "PENGARUH PEMBERIAN PRAVASTATIN TERHADAP KADAR NITRIT OKSIDA PADA PASIEN RISIKO TINGGI PREEKLAMSI"</p> <p>Harap dilakukan pembimbingan dan pendampingan seperti halnya.</p> <p>Kepala Bidang Penelitian dan Inovasi</p>  <p>dr. Muh. Firdaus Kasim, M.Sc NIP:198412012018073001</p> <p><i>Catatan: Lembaran ini diarsipkan oleh Bidang Penelitian dan Inovasi</i></p>		

Lampiran 8 : Cara Kerja KIT Elisa Nitrat oksida



Human Nitric Oxide ELISA Kit

USER INSTRUCTION

Cat.No EI510Hu

Standard Curve Range: 2 μ mol/L - 600 μ mol/L

Sensitivity: 1.12 μ mol/L

Size: 96 wells

Storage: Store the reagents at 2-8°C. For over 6-month storage refer to the expiration date keep it at -20°C. Avoid repeated thaw cycles. If individual reagents are opened it is recommended that the kit be used within 1 month.

***This product is for research use only, not for use in diagnosis procedures. It's highly recommend to read this instruction entirely before use.**

Precision

Intra-Assay Precision (Precision within an assay) Three samples of known concentration were tested on one plate to assess intra-assay precision.

Inter-Assay Precision (Precision between assays) Three samples of known concentration were tested in separate assays to assess inter-assay precision.

$CV(\%) = SD/mean \times 100$

Intra-Assay: CV<8%

Inter-Assay: CV<10%

Intended Use

This sandwich kit is for the accurate quantitative detection of human Nitric Oxide (also known as NO) in serum, plasma, cell culture supernates, cell lysates, tissue homogenates.

Assay Principle

This kit is an Enzyme-Linked Immunosorbent Assay (ELISA). The plate has been pre-coated with human NO antibody. NO present in the sample is added and binds to antibodies coated on the wells. And then biotinylated human NO Antibody is added and binds to NO in the sample. Then Streptavidin-HRP is added and binds to the Biotinylated NO antibody. After incubation unbound

Streptavidin-HRP is washed away during a washing step. Substrate solution is then added and color develops in proportion to the amount of human NO. The reaction is terminated by addition of acidic stop solution and absorbance is measured at 450 nm.

Reagent Provided

Components	Quantity
Standard Solution (640µmol/L)	0.5ml x1
Pre-coated ELISA Plate	12 * 8 well strips x1
Standard Diluent	3ml x1
Streptavidin-HRP	6ml x1
Stop Solution	6ml x1
Substrate Solution A	6ml x1
Substrate Solution B	6ml x1
Wash Buffer Concentrate (25x)	20ml x1
Biotinylated human ANO Antibody	1ml x1
User Instruction	1
Plate Scaler	2 pics
Zipper bag	1 pic

Material Required But Not Supplied

- 37°C±0.5°C incubator
- Absorbent paper
- Precision pipettes and disposable pipette tips
- Clean tubes
- Deionized or distilled water
- Microplate reader with 450 ± 10nm wavelength filter

Precautions

- Prior to use, the kit and sample should be warmed naturally to room temperature 30 minutes.
- This instruction must be strictly followed in the experiment.
- Once the desired number of strips has been removed, immediately reseal the bag to protect the remain from deterioration. Cover all reagents when not in use.
- Make sure pipetting order and rate of addition from well-to-well when pipetting reagents.
- Pipette tips and plate sealer in hand should be clean and disposable to avoid cross-contamination.

- Avoid using the reagents from different batches together.
- Substrate solution B is sensitive to light, don't expose substrate solution B to light for a long time.
- Stop solution contains acid. Please wear eye, hand and skin protection when using this material. Avoid contact of skin or mucous membranes with kit reagent.
- The kit should not be used beyond the expiration date.

Specimen Collection

Serum Allow serum to clot for 10-20 minutes at room temperature. Centrifuge at 2000-3000 RPM for 20 minutes.

Plasma Collect plasma using EDTA or heparin as an anticoagulant. Centrifuge samples for 15 minutes at 2000-3000 RPM at 2 - 8°C within 30 minutes of collection.

Urine Collect by sterile tube. Centrifuge at 2000-3000 RPM for approximately 20 minutes. When collecting pleuroperitoneal fluid and cerebrospinal fluid, please follow the procedures above-mentioned.

Cell Culture Supernatant Collect by sterile tubes when examining secrete components. Centrifuge at 2000-3000 RPM for approximately 20 minutes. Collect the supernatants carefully. When examining the components within the cell, use PBS (pH 7.2-7.4) to dilute cell suspension to the cell concentration of approximately 1 million/ml. Damage cells through repeated freeze-thaw cycles to let out the inside components. Centrifuge at 2000-3000 RPM for approximately 20 minutes.

Tissue and other body fluids Rinse tissues in PBS (pH 7.4) to remove excess blood thoroughly and weigh before homogenization. Mince tissues and homogenize them in PBS (pH7.4) with a glass homogenizer on ice. Thaw at 2-8°C or freeze at -20°C. Centrifuge at 2000-3000 RPM for approximately 20 minutes.

Note

- Sample concentrations should be predicted before being used in the assay. If the sample concentration is not within the range of the standard curve, users must **contact us** to determine the optimal sample for their particular experiments.
- Samples to be used within 5 days should be stored at 2-8°C. Samples should be aliquoted or must be stored at -20°C within 1 month or -80°C within 6 months. Avoid repeated freeze thaw cycles.
- Samples should be brought to room temperature before starting the assay.

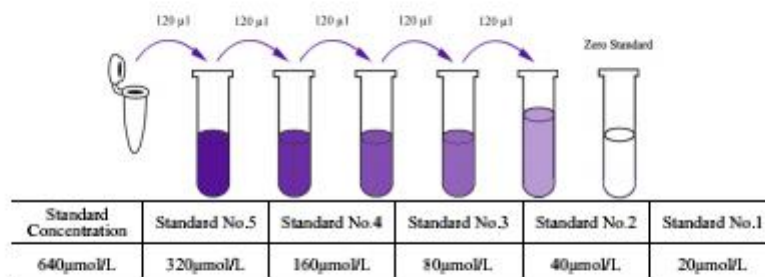
- Centrifuge to collect sample before use.
- Samples containing NaN_3 can't be tested as it inhibits the activity of Horse Radish Peroxidase (HRP).
- Collect the supernatants carefully. When sediments occurred during storage, centrifugation should be performed again.
- Hemolysis can greatly impact the validity of test results. Take care to minimize hemolysis.

**Sample can't be diluted with this kit. Owing to the the material we use to prepare the kit, the sample matrix interference may falsely depress the specificity and accuracy of the assay.*

Reagent Preparation

- All reagents should be brought to room temperature before use.
- **Standard** Reconstitute the 120 μl of the standard (640 $\mu\text{mol/L}$) with 120 μl of standard diluent to generate a 320 $\mu\text{mol/L}$ standard stock solution. Allow the standard to sit for 15 mins with gentle agitation prior to making dilutions. Prepare duplicate standard points by serially diluting the standard stock solution (320 $\mu\text{mol/L}$) 1:2 with standard diluent to produce 160 $\mu\text{mol/L}$, 80 $\mu\text{mol/L}$, 40 $\mu\text{mol/L}$ and 20 $\mu\text{mol/L}$ solutions. Standard diluent serves as the zero standard(0 $\mu\text{mol/L}$). Any remaining solution should be frozen at -20°C and used within one month. Dilution of standard solutions suggested are as follows:

320 $\mu\text{mol/L}$	Standard No.5	120 μl Original Standard + 120 μl Standard Diluent
160 $\mu\text{mol/L}$	Standard No.4	120 μl Standard No.5 + 120 μl Standard Diluent
80 $\mu\text{mol/L}$	Standard No.3	120 μl Standard No.4 + 120 μl Standard Diluent
40 $\mu\text{mol/L}$	Standard No.2	120 μl Standard No.3 + 120 μl Standard Diluent
20 $\mu\text{mol/L}$	Standard No.1	120 μl Standard No.2 + 120 μl Standard Diluent



- **Wash Buffer** Dilute 20ml of Wash Buffer Concentrate 25x into deionized or distilled water to yield 500 ml of 1x Wash Buffer. If crystals have formed in the concentrate, mix gently until the crystals have completely dissolved.

Assay Procedure

1. Prepare all reagents, standard solutions and samples as instructed. Bring all reagents to room temperature before use. The assay is performed at room temperature.
2. Determine the number of strips required for the assay. Insert the strips in the frames for use. The unused strips should be stored at 2-8°C.
3. Add 50µl standard to standard well. **Note:** Don't add antibody to standard well because the standard solution contains biotinylated antibody.
4. Add 40µl sample to sample wells and then add 10µl anti-NO antibody to sample wells, then add 50µl streptavidin-HRP to sample wells and standard wells (Not blank control well). Mix well. Cover the plate with a sealer. Incubate 60 minutes at 37°C.
5. Remove the sealer and wash the plate 5 times with wash buffer. Soak wells with at least 0.35 ml wash buffer for 30 seconds to 1 minute for each wash. For automated washing, aspirate all wells and wash 5 times with wash buffer, overfilling wells with wash buffer. Blot the plate onto paper towels or other absorbent material.
6. Add 50µl substrate solution A to each well and then add 50µl substrate solution B to each well. Incubate plate covered with a new sealer for 10 minutes at 37°C in the dark.
7. Add 50µl Stop Solution to each well, the blue color will change into yellow immediately.
8. Determine the optical density (OD value) of each well immediately using a microplate reader set to 450 nm within 10 minutes after adding the stop solution.

Summary

1. Prepare all reagents, samples and standards.
2. Add sample and ELISA reagent into each well. Incubate for 1 hour at 37°C.
3. Wash the plate 5 times.
4. Add substrate solution A and B. Incubate for 10 minutes at 37°C.
5. Add stop solution and color develops.
6. Read the OD value within 10 minutes.

Calculation of Result

www.bt-laboratory.com | 1008 Junjiang Inter. Bldg., 228 Ningguo Rd., Yangpu Dist., Shanghai, China
Tel: 86 21 31007137 | Fax: 86 21 65 929711 816 | E-mail: sales@bt-laboratory.com

Lampiran 10 : Hasil SPSS

Crosstab

		Pemberian		Total	
		Aspirin	Aspirin+Pravastatin		
Umur	20-35	Count	20	21	41
		% within Pemberian	62.5%	67.7%	65.1%
	>35	Count	12	10	22
		% within Pemberian	37.5%	32.3%	34.9%
Total		Count	32	31	63
		% within Pemberian	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2- sided)	Exact Sig. (2- sided)	Exact Sig. (1- sided)
Pearson Chi-Square	.190 ^a	1	.663		
Continuity Correction ^b	.030	1	.863		
Likelihood Ratio	.191	1	.662		
Fisher's Exact Test				.793	.432
Linear-by-Linear Association	.187	1	.665		
N of Valid Cases	63				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 10.83.

b. Computed only for a 2x2 table

Chi-Square Tests

	Value	df	Asymptotic Significance (2- sided)
Pearson Chi-Square	5.577 ^a	3	.134
Likelihood Ratio	6.486	3	.090
Linear-by-Linear Association	1.937	1	.164

N of Valid Cases	63	
------------------	----	--

a. 4 cells (50.0%) have expected count less than 5. The minimum expected count is .98.

Pendidikan * Pemberian Crosstabulation

		Pemberian		Total	
		Aspirin	Aspirin+Pravastatin		
Pendidikan	Pendidikan Dasar	Count	13	18	31
		% within Pemberian	40.6%	58.1%	49.2%
	Pendidikan Tinggi	Count	19	13	32
		% within Pemberian	59.4%	41.9%	50.8%
Total		Count	32	31	63
		% within Pemberian	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2- sided)	Exact Sig. (2- sided)	Exact Sig. (1- sided)
Pearson Chi-Square	1.916 ^a	1	.166		
Continuity Correction ^b	1.282	1	.258		
Likelihood Ratio	1.926	1	.165		
Fisher's Exact Test				.211	.129
Linear-by-Linear Association	1.886	1	.170		
N of Valid Cases	63				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 15.25.

b. Computed only for a 2x2 table

Crosstab

		Pemberian		Total
		Aspirin	Aspirin+Pravastatin	

Paritas	Nulipara	Count	3	4	7
		% within Pemberian	9.4%	12.9%	11.1%
	>1 Anak	Count	29	27	56
		% within Pemberian	90.6%	87.1%	88.9%
Total		Count	32	31	63
		% within Pemberian	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2- sided)	Exact Sig. (2- sided)	Exact Sig. (1- sided)
Pearson Chi-Square	.198 ^a	1	.656		
Continuity Correction ^b	.002	1	.964		
Likelihood Ratio	.199	1	.656		
Fisher's Exact Test				.708	.482
Linear-by-Linear Association	.195	1	.659		
N of Valid Cases	63				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 3.44.

b. Computed only for a 2x2 table

Crosstab

			Pemberian		Total
			Aspirin	Aspirin+Pravastatin	
IMT	Underweight	Count	1	3	4
		% within Pemberian	3.1%	9.7%	6.3%
	Normal	Count	14	13	27
		% within Pemberian	43.8%	41.9%	42.9%
	Obesitas	Count	17	15	32
		% within Pemberian	53.1%	48.4%	50.8%
Total		Count	32	31	63
		% within Pemberian	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2- sided)
Pearson Chi-Square	1.146 ^a	2	.564
Likelihood Ratio	1.193	2	.551
Linear-by-Linear Association	.528	1	.467
N of Valid Cases	63		

a. 2 cells (33.3%) have expected count less than 5. The minimum expected count is 1.97.

Paired Samples Statistics kelompok aspirin

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Cholesterol Sebelum	248.42	32	54.296	9.049
	Cholesterol Sesudah	269.86	32	77.955	12.992
Pair 2	LDL Sebelum	180.31	32	64.881	11.339
	LDL Sesudah	172.68	32	53.881	9.525
Pair 3	HDL Sebelum	51.08	32	42.093	7.015
	HDL Sesudah	46.39	32	6.838	1.140
Pair 4	TG Sebelum	187.44	32	93.662	15.610
	TG Sesudah	245.00	32	137.552	22.925

Paired Samples Test kelompok aspirin

Mean	Std. Deviation	Paired Differences		t	df	Sig. (2- tailed)
		Std. Error Mean	95% Confidence Interval of the Difference			

					Lower	Upper			
Pair 1	Cholesterol Sebelum - Cholesterol Sesudah	-21.444	72.891	12.149	-46.107	3.218	-1.765	31	.086
Pair 2	LDL Sebelum - LDL Sesudah	76.637	69.096	12.215	-17.274	32.549	.625	31	.536
Pair 3	HDL Sebelum - HDL Sesudah	4.694	42.547	7.091	-9.702	19.090	.662	31	.512
Pair 4	TG Sebelum - TG Sesudah	-57.556	124.972	20.829	-99.840	-15.271	-2.763	31	.009

Paired Samples Statistics kelompok pravastatin

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Cholesterol Sebelum	229.77	31	51.339	9.221
	Cholesterol Sesudah	262.29	31	73.027	13.116
Pair 2	LDL Sebelum	152.12	31	48.056	8.631
	LDL Sesudah	161.73	31	55.023	9.882
Pair 3	HDL Sebelum	45.43	31	7.282	1.308
	HDL Sesudah	45.65	31	6.022	1.082
Pair 4	TG Sebelum	168.21	31	71.517	12.845
	TG Sesudah	301.16	31	166.953	29.986

Paired Samples Test kelompok pravastatin

		Paired Differences				t	df	Sig. (2-tailed)	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower				Upper
Pair 1	Cholesterol Sebelum - Cholesterol Sesudah	-32.516	72.261	12.978	-59.022	-6.011	-2.505	30	.018

Pair 2	LDL Sebelum - LDL Sesudah	-9.616	68.713	12.341	-34.820	15.588	-.779	30	.442
Pair 3	HDL Sebelum - HDL Sesudah	-.219	10.138	1.821	-3.938	3.499	-.120	30	.905
Pair 4	TG Sebelum - TG Sesudah	-132.952	130.159	23.377	-180.694	-85.209	-5.687	30	.000

Paired Samples Statistics MAP

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	MAPsebelum Aspirin	92.7178	32	13.35149	2.36023
	MAPsesudah Aspirin	108.4281	32	17.13102	3.02836
Pair 2	MAP Sebelum Pravastatin	93.8994	31	11.57059	2.07814
	MAP Sesudah Pravastatin	109.2935	31	16.26813	2.92184

Crosstab

		Pemberian			
		Aspirin	Aspirin+Pravastatin	Total	
Hipertensi	Ya	Count	7	7	14
		% within Pemberian	21.9%	22.6%	22.2%
	Tidak	Count	25	24	49
		% within Pemberian	78.1%	77.4%	77.8%
Total	Count	32	31	63	
	% within Pemberian	100.0%	100.0%	100.0%	

Chi-Square Tests

	Value	df	Asymptotic Significance (2- sided)	Exact Sig. (2- sided)	Exact Sig. (1- sided)
Pearson Chi-Square	.005 ^a	1	.946		
Continuity Correction ^b	.000	1	1.000		

Likelihood Ratio	.005	1	.946		
Fisher's Exact Test				1.000	.592
Linear-by-Linear Association	.004	1	.947		
N of Valid Cases	63				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 6.89.

b. Computed only for a 2x2 table

Crosstab

		Pemberian			
		Aspirin	Aspirin+Pravastatin	Total	
Riwayat Preklamsia	Ya	Count	12	16	28
		% within Pemberian	37.5%	51.6%	44.4%
	Tidak	Count	20	15	35
		% within Pemberian	62.5%	48.4%	55.6%
Total	Count	32	31	63	
	% within Pemberian	100.0%	100.0%	100.0%	

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.270 ^a	1	.260		
Continuity Correction ^b	.763	1	.382		
Likelihood Ratio	1.274	1	.259		
Fisher's Exact Test				.315	.191

Linear-by-Linear Association	1.250	1	.264	
N of Valid Cases	63			

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 13.78.

b. Computed only for a 2x2 table

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Aspirin	143.7195034	32	99.23695755	17.54278141
	Aspirin	106.7802769	32	123.98649370	21.91792262
Pair 2	Aspirin+Pravastatin	162.0232	31	126.75328	22.76556
	Aspirin+Pravastatin	82.6042	31	81.15458	14.57579

Paired Samples Test

		Paired Differences							Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	
					Lower	Upper			
Pair 1	Aspirin - Aspirin	36.93922656	145.25009834	25.67683238	-15.42901833	89.30747146	1.439	31	.160
Pair 2	Aspirin+Pravastatin - Aspirin+Pravastatin	79.41893	127.12427	22.83219	32.78937	126.04849	3.478	30	.002

preklamisa * Pemberian Crosstabulation

preklamisa	Ya	Count	Pemberian		Total
			Aspirin	Aspirin+Pravastatin	
			11	18	29

	% within Pemberian	34.4%	58.1%	46.0%
Tidak	Count	21	13	34
	% within Pemberian	65.6%	41.9%	54.0%
Total	Count	32	31	63
	% within Pemberian	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2- sided)	Exact Sig. (2- sided)	Exact Sig. (1- sided)
Pearson Chi-Square	3.557 ^a	1	.059		
Continuity Correction ^b	2.667	1	.102		
Likelihood Ratio	3.591	1	.058		
Fisher's Exact Test				.079	.051
Linear-by-Linear Association	3.501	1	.061		
N of Valid Cases	63				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 14.27.

b. Computed only for a 2x2 table

BBL * pbr Crosstabulation

		intervensi		Total	
		Aspirin	Aspirin+Pravast atin		
BBL	<2500	Count	7	8	15
		% within pbr	21.9%	25.8%	23.8%
	2500-4000	Count	23	23	46
		% within pbr	71.9%	74.2%	73.0%
	>4000	Count	2	0	2
		% within pbr	6.3%	0.0%	3.2%
Total		Count	32	31	63
		% within pbr	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2- sided)
Pearson Chi-Square	2.051 ^a	2	.359
Likelihood Ratio	2.823	2	.244
Linear-by-Linear Association	.707	1	.400
N of Valid Cases	63		

a. 2 cells (33.3%) have expected count less than 5. The minimum expected count is .98.

Test Statistics^a

	Cholesterol Sesudah - Cholesterol Sebelum	LDL Sesudah - LDL Sebelum	HDL Sesudah - HDL Sebelum	TG Sesudah - TG Sebelum
Z	-2.632 ^b	-.898 ^b	-.751 ^b	-4.800 ^b
Asymp. Sig. (2-tailed)	.008	.369	.452	.000

a. Wilcoxon Signed Ranks Test

b. Based on negative ranks.

Lampiran 11

KARTU KONTROL OBAT

NAMA:
 UMUR:
 HPHT:
 USIA KEHAMILAN:
 TAKSIRAN PERSALINAN
 KELOMPOK:

2018

2019

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