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Lampiran

Lampiran 1. Formulir demografi pasien penelitian

FORMULIR PASIEN PENELITIAN

Tanggal Pemeriksaan		Pemeriksa		Jam	
Identitas Pasien					
Nomor Rekam Medis		RS asal			
Nama					
Umur/ Tanggal lahir tahun/ - - (dd – mm – yyyy)				
Alamat / No telepon					
Jenis kelamin	1. ♂ ♀	2.	Pendidikan terakhir		
Hasil pengukuran	TB = cm; BB = kg; IMT = kg/m ²				
Pekerjaan					
Berobat DM teratur	Ya/Tidak				
Lama menderita DM	... tahun				
Hipertensi	Ya/Tidak				
Dislipidemia	Ya/Tidak				
Riwayat merokok dalam 1 tahun terakhir	Ya/Tidak				
Berapa lama anda terpapar sinar matahari ?					
Berapa banyak anda minum susu setiap hari ?					
Kriteria Inklusi					
Pertanyaan			Ya	Tdk	
1. Apakah anda didiagnosis neuropati diabetika berdasarkan anamnesis, pemeriksaan fisik, dan pemeriksaan penunjang?					
2. Apakah anda terdaftar dalam rekam medis Rumah Sakit Wahidin Sudirohusodo?					
3. Apakah anda berusia antara 40-65 tahun?					
4. Apakah anda bersedia diikutsertakan dalam penelitian ini dan menandatangani <i>informed consent</i> ?					

Kriteria Eksklusi		
Pertanyaan	Ya	Tdk
1. Apakah anda mengalami amputasi ekstremitas atas atau bawah?		
2. Apakah anda sedang hamil atau menyusui?		
3. Apakah anda mengalami nyeri akut dan berat pada ekstremitas atas atau bawah yang membutuhkan injeksi analgesic?		
4. Apakah ada penyebab nyeri yang lain seperti infeksi atau PAD (<i>Peripheral Arterial Disease</i>)?		
5. Apakah anda memiliki penyakit gagal ginjal, gagal hati, gagal jantung, artritis inflamasi, hiperparatiroidisme, alkoholisme, dan malnutrisi?		

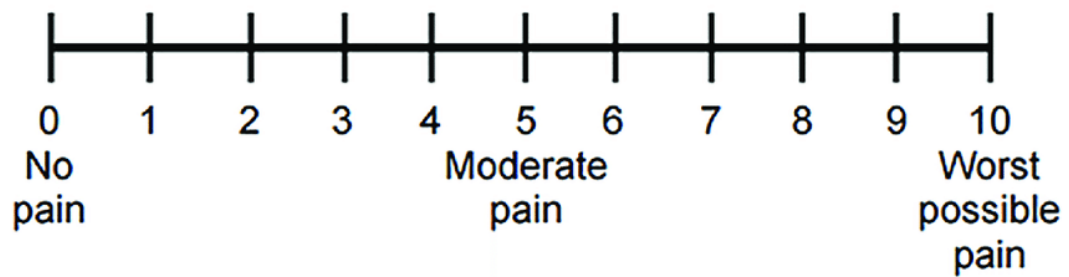
Saya bersedia/tidak bersedia untuk ikut dalam penelitian ini tanpa paksaan dari pihak manapun.

Mengetahui,

(.....)

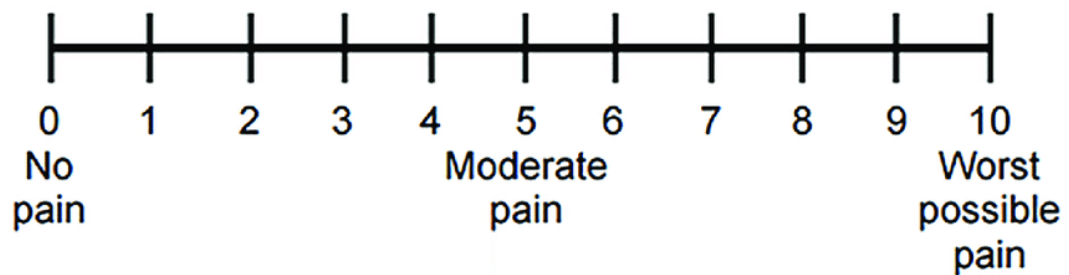
Lampiran 1 Numeric Pain Rating Scale Sebelum

0–10 Numeric Pain Rating Scale



Numeric Pain Rating Scale Sesudah














0–10 Numeric Pain Rating Scale



Lampiran 2 Kuesioner painDETECT

<i>painDETECT</i>	KUESIONER NYERI
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Tanggal:	Nama Pasien:	Usia:
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<p>Catatan : 0= tidak ada nyeri, 1-3= nyeri ringan, 4-7= nyeri sedang, 8-10= nyeri berat Bagaimana penilaian rasa nyeri Anda sekarang, pada saat ini?</p> <table border="1" style="width: 100%; text-align: center;"> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td></tr> <tr><td colspan="5">Tidak ada</td><td colspan="6">maks</td></tr> </table> <p>Seberapa kuat rasa nyeri yang terberat selama 4minggu terakhir ?</p> <table border="1" style="width: 100%; text-align: center;"> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td></tr> <tr><td colspan="5">Tidak ada</td><td colspan="6">maks</td></tr> </table> <p>Seberapa kuat " rata-rata" rasa nyeri selama 4 minggu terakhir?</p> <table border="1" style="width: 100%; text-align: center;"> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td></tr> <tr><td colspan="5">Tidak ada</td><td colspan="6">maks</td></tr> </table> <p>Tandai gambar yang paling tepat menggambarkan rasa nyeri yang Anda alami</p> <table style="width: 100%;"> <tr> <td style="text-align: center;"></td> <td>Nyeri menetap, terus- menerus, sedikit fluktuasi</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;"></td> <td>Nyeri menetap disertai serangan nyeri yang lebih kuat</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;"></td> <td>Nyeri hilang dan timbul tanpa ada rasa sakit diantaranya</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;"></td> <td>Serangan-serangan nyeri diantara rasa nyeri yang ada</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	0	1	2	3	4	5	6	7	8	9	10	Tidak ada					maks						0	1	2	3	4	5	6	7	8	9	10	Tidak ada					maks						0	1	2	3	4	5	6	7	8	9	10	Tidak ada					maks							Nyeri menetap, terus- menerus, sedikit fluktuasi	<input type="checkbox"/>		Nyeri menetap disertai serangan nyeri yang lebih kuat	<input type="checkbox"/>		Nyeri hilang dan timbul tanpa ada rasa sakit diantaranya	<input type="checkbox"/>		Serangan-serangan nyeri diantara rasa nyeri yang ada	<input type="checkbox"/>	<p style="text-align: center;">Tandai lokasi nyeri pada tubuh Anda</p> <div style="text-align: center;">  </div> <p style="text-align: center;">Apakah rasa nyeri menjalar kebagian lain dari tubuh Anda? Ya Tidak Jika ya, gambarkan arah penjalaran itu</p>
0	1	2	3	4	5	6	7	8	9	10																																																																					
Tidak ada					maks																																																																										
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	Nyeri hilang dan timbul tanpa ada rasa sakit diantaranya	<input type="checkbox"/>																																																																													
	Serangan-serangan nyeri diantara rasa nyeri yang ada	<input type="checkbox"/>																																																																													

Apakah Anda menderita sensasi seperti terbakar (panas menyengat) di daerah nyeri?	tak pernah <input type="checkbox"/>	hampir tidak terasa <input type="checkbox"/>	sedikit <input type="checkbox"/>	sedang <input type="checkbox"/>	kuat <input type="checkbox"/>	sangat kuat <input type="checkbox"/>
Apakah Anda merasa kesemutan, seperti ditusuk-tusuk di daerah nyeri (seperti semut merayap atau kesetrum)?	tak pernah <input type="checkbox"/>	hampir tidak terasa <input type="checkbox"/>	sedikit <input type="checkbox"/>	sedang <input type="checkbox"/>	kuat <input type="checkbox"/>	sangat kuat <input type="checkbox"/>
Adakah sentuhan ringan (seperti pakaian/kain atau selimut) memberi rasa nyeri?	tak pernah <input type="checkbox"/>	hampir tidak terasa <input type="checkbox"/>	sedikit <input type="checkbox"/>	sedang <input type="checkbox"/>	kuat <input type="checkbox"/>	sangat kuat <input type="checkbox"/>
Apakah Anda merasakan serangan nyeri mendadak seperti sengatan listrik/kesetrum?	tak pernah <input type="checkbox"/>	hampir tidak terasa <input type="checkbox"/>	sedikit <input type="checkbox"/>	sedang <input type="checkbox"/>	kuat <input type="checkbox"/>	sangat kuat <input type="checkbox"/>
Apakah (air mandi) yang dingin atau panas dapat menimbulkan rasa nyeri?	tak pernah <input type="checkbox"/>	hampir tidak terasa <input type="checkbox"/>	sedikit <input type="checkbox"/>	sedang <input type="checkbox"/>	kuat <input type="checkbox"/>	sangat kuat <input type="checkbox"/>
Apakah Anda menderita ba'al/rasa tebal atau mati rasa pada daerah nyeri?	tak pernah <input type="checkbox"/>	hampir tidak terasa <input type="checkbox"/>	sedikit <input type="checkbox"/>	sedang <input type="checkbox"/>	kuat <input type="checkbox"/>	sangat kuat <input type="checkbox"/>
Apakah tekanan ringan seperti tekanan jari pada area sakit, menimbulkan rasa nyeri?	tak pernah <input type="checkbox"/>	hampir tidak terasa <input type="checkbox"/>	sedikit <input type="checkbox"/>	sedang <input type="checkbox"/>	kuat <input type="checkbox"/>	sangat kuat <input type="checkbox"/>
(untuk diisi oleh dokter)	tak pernah	hampir tidak terasa	sedikit	sedang	kuat	sangat kuat
	X0 0	X1	X2	X3	X4	X5






Jumlah skor dari 35

<i>painDETECT</i>	PENILAIAN KUESIONER NYERI
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Tanggal:	Nama Pasien:	Usia:
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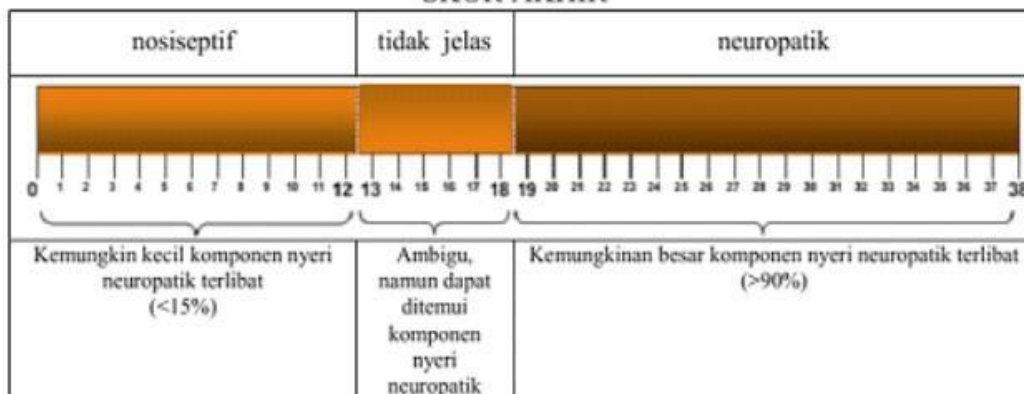
Pindahkan skoring dari kuesioner nyeri
Jumlah skor :

Jumlahkan skor dengan angka berikut, tergantung pada pola dan perjalanan nyeri yang ditandai. Kemudian hitung jumlah skor akhir:

	Nyeri menetap, terus-menerus, sedikit fluktuasi	0	
	Nyeri menetap disertai serangan nyeri yang lebih kuat	-1	Jika ditandai, atau
	Nyeri hilang dan timbul tanpa ada rasa sakit diantaranya	+1	Jika ditandai, atau
	Serangan-serangan nyeri diantara rasa nyeri yang ada	+1	Jika ditandai
	Rasa nyeri menjalar?	+2	Jika ya

SKOR AKHIR □ □

HASIL SKORING SKOR AKHIR








Lembar ini tidak menggantikan diagnosis medis.
Lembar ini digunakan untuk melakukan skrining adanya komponen nyeri neuropatik.
 Pengembangan / Referensi: R. Freynhagen, R. Baron, U. Gockel, T.R. Tolle/Curr Med Res Opin., Vol. 22, No.10 (2006)
 ©2005Pfizer Pharma GmbH

Tanggal :	Nama Pasien :	Usia :
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Pindahkan skoring dari kuesioner nyeri
Jumlah skor :

Jumlahkan skor dengan angka berikut, tergantung pada pola dan penjalaran nyeri yang ditandai. Kemudian hitung jumlah skor akhir :

	Nyeri menetap, terus menerus, sedikit fluktuasi	0	
	Nyeri menetap disertai serangan nyeri yang lebih kuat		Jika ditandai, atau
	Nyeri hilang dan timbul tanpa ada rasa sakit diantaranya	+1	Jika ditandai, atau
	Serangan-serangan nyeri diantara rasa	+1	Jika ditandai
	Rasa nyeri menjalar?	+2	Jika ya

SKOR AKHIR

Lembar ini tidak menggantikan diagnosis medis.

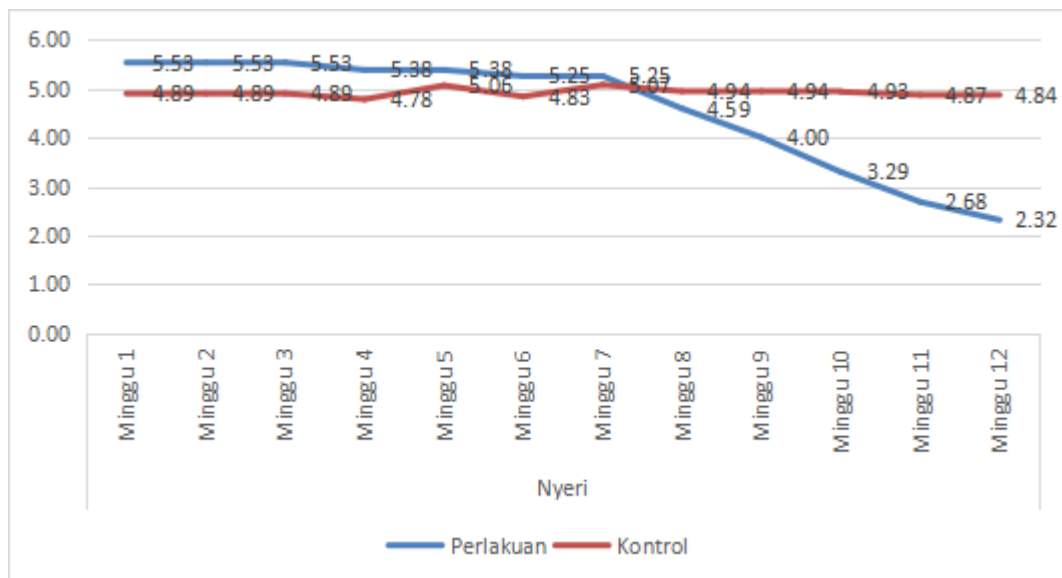
Laboratorium	
Vitamin D serum	

Lampiran 1.

 RUMAH SAKIT UNHAS	SURAT IZIN PENELITIAN	
	Nomor: 4175/UN4.24.1.2/PT.01.04/2022	Tanggal 19 Mei 2022
FORMULIR 2	Kepada Yth Kepala Ruang Laboratorium Penelitian	
BIDANG PENELITIAN DAN INOVASI		
<p>Dengan hormat,</p> <p>Dengan ini menerangkan bahwa peneliti/ mahasiswa berikut ini:</p> <p>Nama : dr. Ade Sofiyani</p> <p>NIM / NIP : C155172009</p> <p>Institusi : Departemen Neurologi, PPDS Fakultas Kedokteran Unhas, Universitas Hasanuddin Makassar</p> <p>Kode penelitian : 220519_1</p> <p>Akan melakukan pengambilan data/ analisa bahan hayati:</p> <p>Terhitung : 19 Mei 2022 s/d 30 Juni 2022</p> <p>Jumlah Subjek/Sample : 40</p> <p>Jenis Data : Data Primer: Elisa</p> <p>Untuk penelitian dengan judul:</p> <p>"PENGARUH PEMBERIAN SUPLEMEN VITAMIN D TERHADAP DERAJAT NYERI NEUROPATIK PADA PENDERITA NEUROPATI DIABETIK "</p> <p>Harap dilakukan pembimbingan dan pendampingan seperlunya.</p> <p>Kepala Bidang Penelitian dan Inovasi</p> <p> dr. Aslim Taslim, Sp.Onk.Rad, M.Kes NIP.198304252012121003</p> <p><i>Catatan: Lembaran ini diarsipkan oleh Bidang Penelitian dan Inovasi</i></p>		

Lampiran 2.

Kelompok	Nyeri											
	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12
Perlakuan	5.53	5.53	5.53	5.38	5.38	5.25	5.25	4.59	4.00	3.29	2.68	2.32
Kontrol	4.89	4.89	4.89	4.78	5.06	4.83	5.07	4.94	4.94	4.93	4.87	4.84
Jumlah	5.21	5.21	5.21	5.06	5.21	5.07	5.17	4.76	4.47	4.03	3.65	3.58



Lampiran 3.



REKOMENDASI PERSETUJUAN ETIK

Nomor : 179/UN4.6.4.5.31/ PP36/ 2022

Tanggal: 18 April 2022

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

No Protokol	UH22030123	No Sponsor Protokol	
Peneliti Utama	dr. Ade Sofiyani	Sponsor	
Judul Peneliti	PENGARUH PEMBERIAN SUPLEMEN VITAMIN D TERHADAP DERAJAT NYERI NEUROPATIK PADA PENDERITA NEUROPATI DIABETIK		
No Versi Protokol	2	Tanggal Versi	13 April 2022
No Versi PSP	2	Tanggal Versi	13 April 2022
Tempat Penelitian	RS Dr. Wahidin Sudirohusodo Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input checked="" type="checkbox"/> Fullboard Tanggal 23 Maret 2022	Masa Berlaku 18 April 2022 sampai 18 April 2023	Frekuensi review lanjutan
Ketua KEP Universitas Hasanuddin	Nama Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K)	Tanda tangan	
Sekretaris KEP Universitas Hasanuddin	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.**Uji Normalitas Data**

Shapiro-Wilk normality test		
W	0.8545	0.7829
P value	0.0080	0.0007
Passed normality test (alpha=0.05)?	No	No
P value summary	**	***

Uji Korelasi NPRS dengan D25(OH) baseline

Spearman r	
r	-0.5682
95% confidence interval	-0.7556 to -0.2948
P value	
P (two-tailed)	0.0002
P value summary	***
Exact or approximate P value?	Approximate
Significant? (alpha = 0.05)	Yes
Number of XY Pairs	38

Uji Korelasi NPRS dengan D2(OH) After

Spearman r	
r	-0.5836
95% confidence interval	-0.7653 to -0.3156
P value	
P (two-tailed)	0.0001
P value summary	***
Exact or approximate P value?	Approximate
Significant? (alpha = 0.05)	Yes
Number of XY Pairs	38