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Lampiran Persetujuan Etik



REKOMENDASI PERSETUJUAN ETIK

Nomor : 363/UN4.6.4.5.31/ PP36/ 2022

Tanggal: 25 Juli 2022

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

No Protokol	UH22050219	No Sponsor Protokol	
Peneliti Utama	dr. Diza Khairina Mukhlisa	Sponsor	
Judul Penelitian	PENGARUH LATIHAN FISIK TERHADAP PERUBAHAN KAPASITAS FUNGSIONAL DAN KUALITAS HIDUP PADA PASIEN KANKER PAYUDARA YANG MENJALANI KEMOTERAPI		
No Versi Protokol	2	Tanggal Versi	15 Juli 2022
No Versi PSP	2	Tanggal Versi	15 Juli 2022
Tempat Penelitian	RS Universitas Hasanuddin dan RSUP Dr. Wahidin Sudirohusodo Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input checked="" type="checkbox"/> Fullboard Tanggal 2 Juni 2022	Masa Berlaku 25 Juli 2022 sampai 25 Juli 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 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

DATA

No. Sampel	Umur (Tahun)	Obat Kemoterapi	Jarak Pre-Kemoterapi	Jarak Post-Kemoterapi	VO2 Max Pre-Kemoterapi	VO2 Max Post-Kemoterapi	METs Pre-Kemoterapi	METs Post Kemoterapi
1	54	Doxorubicin 80mg + Docetaxel 110 mg	389	340	21,104	18,164	6,02971429	5,18971429
2	46	Paxus 300 miligram per intravena, epirubicin 80 miligram per intravena	345	280	19,556	15,656	5,58742857	4,47314286
3	44	Paclitaxel 250 mg + Epirubicin 75 mg + Cyclophosphamide 750 mg	335	288	18,176	15,356	5,19314286	4,38742857
4	28	Doxorubicin 90mg + Cyclophosphamide 900mg	288	245	16,864	14,284	4,81828571	4,08114286
5	46	Brexel 120mg + Doxorubicin 80mg + Cyclophosphamide 800mg	325	270	17,68	14,38	5,05142857	4,10857143
6	41	Paclitaxel 260mg, Epirubicin 70mg, Cyclophosphamide 700mg	326	290	18,416	16,256	5,26171429	4,64457143
7	45	Paclitaxel 270mg + Epirubicin 90mg	328	270	17,756	14,276	5,07314286	4,07885714
8	36	Brexel 120mg + Doxorubicin 85mg + Cyclophosphamide 850 mg	380	350	22,956	21,156	6,55885714	6,04457143
9	46	Brexel 120mg + Doxorubicin 82mg + Cyclophosphamide 800mg	285	245	15,644	13,244	4,46971429	3,784
10	55	Brexel 120mg + Doxorubicin 80mg + Cyclophosphamide 800mg	369	335	18,76	16,72	5,36	4,77714286
11	47	Brexel 120mg + Doxorubicin 80mg + Cyclophosphamide 800mg	289	245	16,352	13,712	4,672	3,91771429
12	42	Doxorubicin 70mg + Paclitaxel 260mg	288	250	16,032	13,752	4,58057143	3,92914286

13	34	doxorubicin 100mg + Cyclophosphamide 1000mg + Docetaxel 180mg	310	275	19,172	17,072	5,47771429	4,87771429
14	63	Fankopac 330mg + Epirubicin 80mg	285	245	13,096	10,696	3,74171429	3,056
15	39	Doxorubicin 90mg + Cyclophosphamide 900mg	388	355	22,032	20,052	6,29485714	5,72914286
16	60	brexel 80 mg perintravena, doxorubicin 50 mg per intravena, cisplatin 50 mg per intraperintravenavena	325	288	15,964	13,744	4,56114286	3,92685714
17	53	Brexel 130mg, Epirubicin 80mg	438	415	24,252	22,872	6,92914286	6,53485714
18	61	Brexel 110mg + Epirubicin 70mg + Cyclophosphamide 700mg	310	285	15,012	13,512	4,28914286	3,86057143
19	51	Brexel 120 milligram per intravena, Doxorubicin 80 mg milligram per intravena, cyclophosphamide 800 milligram per intravena	326	295	16,752	14,892	4,78628571	4,25485714
20	50	Paclitaxel 270mg + Epirubicin 90mg	347	310	17,96	15,74	5,13142857	4,49714286
21	53	Brexel 120 milligram per intravena, Doxorubicin 80 mg milligram per intravena, cyclophosphamide 800 milligram per intravena	359	315	19,356	16,716	5,53028571	4,776
22	60	Brexel 120 milligram per intravena, Doxorubicin 80 mg milligram per intravena, cyclophosphamide 800 milligram per intravena	348	310	17,916	15,636	5,11885714	4,46742857
23	44	Fankopac 330mg + Epirubicin 80mg	312	270	17,316	14,796	4,94742857	4,22742857
24	47	Brexel 130mg, Epirubicin 80mg	421	400	23,856	22,596	6,816	6,456

25	63	Paclitaxel 270mg + Epirubicin 90mg	326	285	15,608	13,148	4,45942857	3,75657143
26		Brexel 120 milligram per intravena, Doxorubicin 80 mg milligram per intravena, cyclophosphamide 800 milligram per intravena						
	44		317	265	17,148	14,028	4,89942857	4,008
27		Cyclophosphamide 800 mg, doxorubicin 80 mg, 5-FU 800 mg						
	44		354	324	19,524	17,724	5,57828571	5,064
28	60	Fonkopac (Cisplatin) 330mg + Epirubicin 80mg	367	344	18,796	17,416	5,37028571	4,976
29		Brexel 120mg + Doxorubicin 80mg + Cyclophosphamide 800mg						
	44		294	250	16,756	14,116	4,78742857	4,03314286
30		Brexel + Doxorubicin + Cyclophosphamide						
	51		379	345	21,076	19,036	6,02171429	5,43885714
31	38	Brexel + Doxorubicin + Cyclophosphamide						
			378	345	20,756	18,776	5,93028571	5,36457143
32	47	Doxorubicin 70mg + Paclitaxel 260mg						
			318	265	16,896	13,716	4,82742857	3,91885714
33		Brexel + Doxorubicin + Cyclophosphamide						
	51		315	265	16,3	13,3	4,65714286	3,8
34	58	Paclitaxel + Epirubicin + Cyclophosphamide						
			446	420	23,068	21,508	6,59085714	6,14514286
35		Paclitaxel + Epirubicin + Cyclophosphamide						
	55		327	270	18,06	14,64	5,16	4,18285714
36		doxorubicin 100mg + Cyclophosphamide 1000mg + Docetaxel 180mg						
	55		364	328	19,656	17,496	5,616	4,99885714
37		docetaxel 100 milligram per intravena, epirubicin 75 milligram per intravena						
	51		364	325	19,708	17,368	5,63085714	4,96228571
38	60	Paclitaxel + Epirubicin + Cyclophosphamide						
			445	430	23,684	22,784	6,76685714	6,50971429
39	38	Doxorubicin + Paclitaxel	350	325	19,544	18,044	5,584	5,15542857

40	65	Paclitaxel 280mg + Epirubicin 80mg + Cyclophosphamide 800mg	388	350	19,484	17,204	5,56685714	4,91542857
41		Brexel (Docetaxel) + Epirubicin + Cyclophosphamide						
	70		326	285	14,724	12,264	4,20685714	3,504
42	58	Brexel + Doxorubicin + Cyclophosphamide	410	375	21,636	19,536	6,18171429	5,58171429
43	56	Brexel + Doxorubicin + Cyclophosphamide	326	270	16,336	12,976	4,66742857	3,70742857
44		Brexel (Docetaxel) + Epirubicin + Cyclophosphamide						
	32		410	375	24,08	21,98	6,88	6,28
45	44	Paclitaxel + Epirubicin + Cyclophosphamide	296	245	15,732	12,672	4,49485714	3,62057143
46	48	Paclitaxel + Epirubicin + Cyclophosphamide	293	252	15,032	12,572	4,29485714	3,592
47		Brexel 110mg + Epirubicin 70mg + Cyclophosphamide 700mg						
	46		432	410	24,464	23,144	6,98971429	6,61257143
48	49	Doxorubicin 90mg + Cyclophosphamide 900mg	364	328	19,552	17,392	5,58628571	4,96914286
49		Paclitaxel 260mg, Epirubicin 70mg, Cyclophosphamide 700mg						
	42		355	310	20,572	17,872	5,87771429	5,10628571