

LAMPIRAN 1



KEMENTERIAN PENDIDIKAN, KEBUDAYAAN, RISET DAN TEKNOLOGI
UNIVERSITAS HASANUDDIN FAKULTAS KEDOKTERAN
KOMITE ETIK PENELITIAN UNIVERSITAS HASANUDDIN
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..MMed,PhD, SpGK TELP. 081241850858, 0411 5780103, Fax : 0411-581431

REKOMENDASI PERSETUJUAN ETIK

Nomor : 992/UN4.6.4.5.31/ PP36/ 2024

Tanggal: 15 Nopember 2024

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

No Protokol	UH24110923	No Sponsor	
Peneliti Utama	dr. Fajri Nurjamil	Sponsor	
Judul Peneliti	Perbandingan Regimen Respon Therapy Menggunakan Doxorubicin Dan Cisplatin Terhadap qEASL pada Pasien Intermediate Stage Hepatocellular Carcinoma		
No Versi Protokol	1	Tanggal Versi	8 Nopember 2024
No Versi PSP		Tanggal Versi	
Tempat Penelitian	RSUP Dr.Wahidin Sudirohusodo Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal	Masa Berlaku 15 Nopember 2024 sampai 15 Nopember 2025	Frekuensi review lanjutan
Ketua KEP Universitas Hasanuddin	Prof. dr. Muh Nasrum Massi, PhD, SpMK, Subsp. Bakt(K)	Tanda tangan 	
Sekretaris KEP Universitas Hasanuddin	dr. Firdaus Hamid, PhD, SpMK(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 2

JK * Kemoterapi

Crosstab

			Kemoterapi		Total
			Cisplatin	Doxorubisin	
JK	Laki-laki	Count	21	25	46
		% within Kemoterapi	72.4%	89.3%	80.7%
	Perempuan	Count	8	3	11
		% within Kemoterapi	27.6%	10.7%	19.3%
Total		Count	29	28	57
		% within Kemoterapi	100.0%	100.0%	100.0%

Crosstab

			Kemoterapi		Total
			Cisplatin	Doxorubisin	
UsiaKat	25-45 tahun	Count	3	9	12
		% within Kemoterapi	10.3%	32.1%	21.1%
	46-55 tahun	Count	17	9	26
		% within Kemoterapi	58.6%	32.1%	45.6%
	56-65 tahun	Count	7	9	16
		% within Kemoterapi	24.1%	32.1%	28.1%
	>65 tahun	Count	2	1	3
		% within Kemoterapi	6.9%	3.6%	5.3%
Total		Count	29	28	57
		% within Kemoterapi	100.0%	100.0%	100.0%

Means

[DataSet3] H:\Kerjaan\Hasil hepatokarsinoma\gabungan cisplatin.sav

Report

Volume

TACI	Mean	N	Std. Deviation	Minimum	Maximum	Median
Pre	762.0690	29	480.42310	64.00	1911.00	637.0000
1	704.6207	29	549.87397	57.00	1934.00	548.0000
2	581.5000	16	459.39090	55.00	1448.00	446.0000
3	729.0000	10	633.63046	29.00	1735.00	651.5000
4	680.6000	5	648.07044	33.00	1446.00	496.0000
Total	702.5955	89	519.33499	29.00	1934.00	542.0000

NPar Tests

Kruskal-Wallis Test

Test Statistics^{a,b}

	Volume
Chi-Square	1.592
df	4
Asymp. Sig.	.810

a. Kruskal Wallis Test

b. Grouping Variable:

TACI

Means

[DataSet3] H:\Kerjaan\Hasil hepatokarsinoma\gabungan doxorubisin.sav

Report

Volume

TACI	Mean	N	Std. Deviation	Median	Minimum	Maximum
Pre	704.7143	28	638.55038	551.0000	55.00	2838.00
1	850.0357	28	722.57679	633.0000	62.00	2854.00
2	808.8889	18	807.23871	658.5000	31.00	2901.00
3	705.6923	13	524.32963	877.0000	27.00	1496.00
4	648.2500	8	481.78441	678.0000	68.00	1489.00
Total	762.6632	95	665.25579	633.0000	27.00	2901.00

NPar Tests**Kruskal-Wallis Test****Test Statistics^{a,b}**

	Volume
Chi-Square	.572
df	4
Asymp. Sig.	.966

a. Kruskal Wallis Test

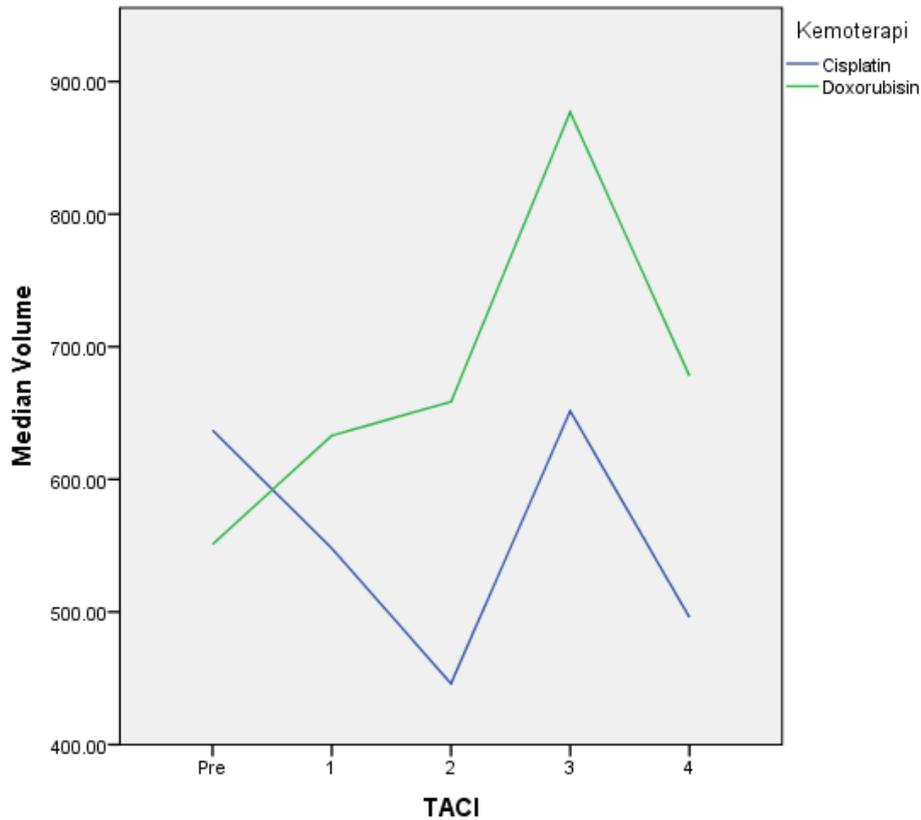
b. Grouping Variable:

TACI

NPar Tests**Mann-Whitney Test****Test Statistics^a**

	Volume
Mann-Whitney U	4198.000
Wilcoxon W	8203.000
Z	-.082
Asymp. Sig. (2-tailed)	.935

a. Grouping Variable: Kemoterapi



Crosstabs

[DataSet2] H:\Kerjaan\Hasil hepatokarsinoma\gabungan cisplatin.sav

qEASL * TACI Crosstabulation

			TACI				Total
			1	2	3	4	
qEASL	PR	Count	1	1	1	0	3
		% within TACI	3.4%	6.3%	10.0%	0.0%	5.0%
	SD	Count	28	14	7	5	54
		% within TACI	96.6%	87.5%	70.0%	100.0%	90.0%
	PD	Count	0	1	2	0	3
		% within TACI	0.0%	6.3%	20.0%	0.0%	5.0%
Total		Count	29	16	10	5	60
		% within TACI	100.0%	100.0%	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	7.839 ^a	6	.250
Likelihood Ratio	7.762	6	.256
Linear-by-Linear Association	.682	1	.409
N of Valid Cases	60		

a. 9 cells (75,0%) have expected count less than 5. The minimum expected count is ,25.

Crosstabs

[DataSet3] H:\Kerjaan\Hasil hepatokarsinoma\gabungan doxorubisin.sav

qEASL * TACI Crosstabulation

			TACI				
			1	2	3	4	Total
qEASL	PR	Count	2	1	1	1	5
		% within TACI	7.1%	5.6%	7.7%	12.5%	7.5%
	SD	Count	24	14	9	6	53
		% within TACI	85.7%	77.8%	69.2%	75.0%	79.1%
	PD	Count	2	3	3	1	9
		% within TACI	7.1%	16.7%	23.1%	12.5%	13.4%
Total		Count	28	18	13	8	67
		% within TACI	100.0%	100.0%	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2.571 ^a	6	.860
Likelihood Ratio	2.537	6	.864
Linear-by-Linear Association	.247	1	.619
N of Valid Cases	67		

a. 8 cells (66,7%) have expected count less than 5. The minimum expected count is ,60.

Crosstabs

[DataSet1] H:\Kerjaan\Hasil hepatokarsinoma\PreTACI dan TACI1.sav

qEASL * Kemoterapi Crosstabulation

			Kemoterapi		
			Cisplatin	Doxorubisin	Total
qEASL	PR	Count	1	2	3
		% within qEASL	33.3%	66.7%	100.0%
	SD	Count	28	24	52
		% within qEASL	53.8%	46.2%	100.0%
	PD	Count	0	2	2
		% within qEASL	0.0%	100.0%	100.0%
Total		Count	29	28	57
		% within qEASL	50.9%	49.1%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2.624 ^a	2	.269
Likelihood Ratio	3.403	2	.182
Linear-by-Linear Association	.190	1	.663
N of Valid Cases	57		

a. 4 cells (66,7%) have expected count less than 5. The minimum expected count is ,98.

Crosstabs

[DataSet5] H:\Kerjaan\Hasil hepatokarsinoma\TAC12.sav

qEASL * Kemoterapi Crosstabulation

			Kemoterapi		Total
			Cisplatin	Doxorubisin	
qEASL	PR	Count	1	1	2
		% within qEASL	50.0%	50.0%	100.0%
	SD	Count	14	14	28
		% within qEASL	50.0%	50.0%	100.0%
	PD	Count	1	3	4
		% within qEASL	25.0%	75.0%	100.0%
Total	Count		16	18	34
	% within qEASL		47.1%	52.9%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	.885 ^a	2	.642
Likelihood Ratio	.929	2	.629
Linear-by-Linear Association	.587	1	.444
N of Valid Cases	34		

a. 4 cells (66,7%) have expected count less than 5. The minimum expected count is ,94.

Crosstabs

[DataSet6] H:\Kerjaan\Hasil hepatokarsinoma\TAC13.sav

qEASL * Kemoterapi Crosstabulation

			Kemoterapi		Total
			Cisplatin	Doxorubisin	
qEASL	PR	Count	1	1	2
		% within qEASL	50.0%	50.0%	100.0%
	SD	Count	7	9	16
		% within qEASL	43.8%	56.3%	100.0%
	PD	Count	2	3	5
		% within qEASL	40.0%	60.0%	100.0%
Total	Count		10	13	23
	% within qEASL		43.5%	56.5%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	.060 ^a	2	.971
Likelihood Ratio	.060	2	.971
Linear-by-Linear Association	.055	1	.815
N of Valid Cases	23		

a. 4 cells (66,7%) have expected count less than 5. The minimum expected count is ,87.

Crosstabs

[DataSet7] H:\Kerjaan\Hasil hepatokarsinoma\TAC14.sav

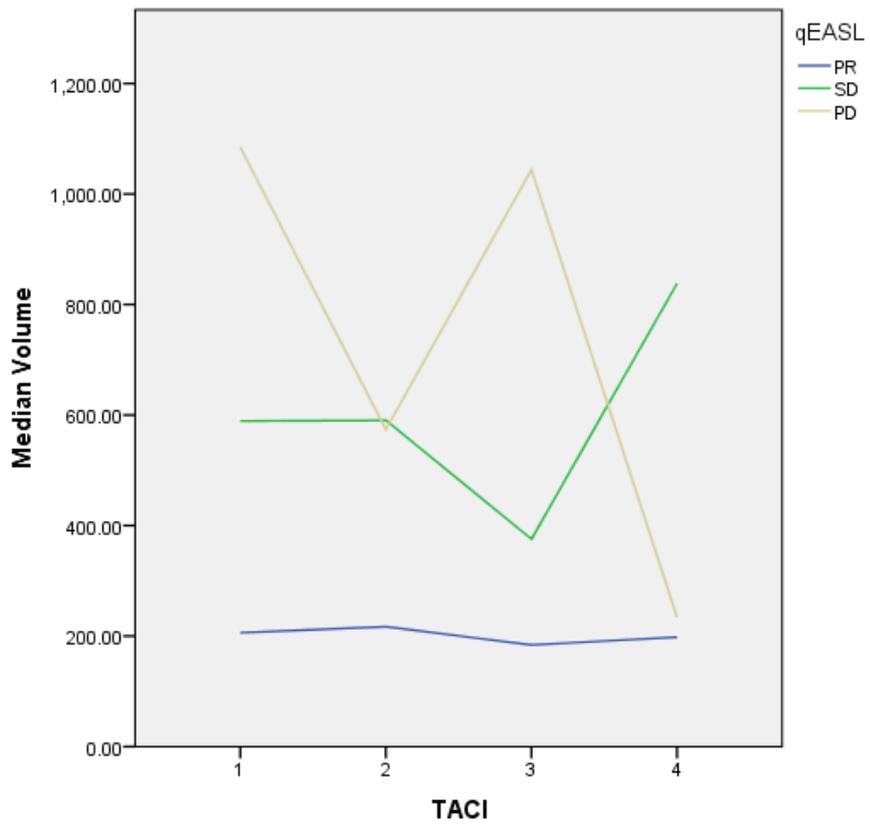
qEASL * Kemoterapi Crosstabulation

			Kemoterapi		Total
			Cisplatin	Doxorubisin	
qEASL PR	Count		0	1	1
	% within qEASL		0.0%	100.0%	100.0%
SD	Count		5	6	11
	% within qEASL		45.5%	54.5%	100.0%
PD	Count		0	1	1
	% within qEASL		0.0%	100.0%	100.0%
Total	Count		5	8	13
	% within qEASL		38.5%	61.5%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	1.477 ^a	2	.478
Likelihood Ratio	2.165	2	.339
Linear-by-Linear Association	.000	1	1.000
N of Valid Cases	13		

a. 5 cells (83,3%) have expected count less than 5. The minimum expected count is ,38.



LAMPIRAN 3 CURICULUM VITAE

Data Umum

Nama : dr. Fajri Nurjamil
Tempat/ Tanggal Lahir : Kelurahan Baro Yaman, 12 Mei 1986
Jenis kelamin : Laki-laki
Alamat: Jalan Medan – Banda Aceh, Kelurahan Gampong Lada, Kecamatan Mutiara Timur. Kab.Pidie – Aceh. 24173
Telepon : +6282198137879
Agama : Islam
Status : Menikah
Pekerjaan : Dokter

Pendidikan:

2004 - 2008: **SARJANA KEDOKTERAN** – Universitas Abulyatama Aceh - Indonesia
2008 - 2011: **PENDIDIKAN PROFESI DOKTER** – Universitas Abulyatama Aceh - Indonesia
2021-Sekarang: **PENDIDIKAN DOKTER SPESIALIS** – Universitas Hasanuddin, Makassar-Indonesia

Pengalaman Kerja:

2012-2013: Dokter tenaga sukarela di Puskesmas Delima.Kab Pidie – Aceh
2013 – 2015: Dokter PTT Pusat Kemenkes RI di Kab.Asmat – Papua
2015 – 2021: Dokter PTT Daerah Kab.Asmat - Papua

Karya Ilmiah/Research Papers:

1. **Perbandingan respon terapi doxorubicin dan cisplatin menggunakan qEASL pada pasien intermediate stage hepatocellular carcinoma**

Symposium / Acara Ilmiah:

1. **PIT PDSRI XVI Sumatera utara – Medan 2023**
2. **Poster Competition PIT PDSRI XVI Sumatera utara – Medan 2023**
3. **Symposium “Raising A Better Abdominal Diagnostic Imaging” Banda Aceh 2023**
4. **Peserta fotografi di Symposium “Raising A Better Abdominal Diagnostic Imaging” Banda Aceh 2023**