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Lampiran 1 : etik penelitian

KEMENTERIAN PENDIDIKAN, KEBUDAYAAN, RISET DAN TEKNOLOGI
UNIVERSITAS HASANUDDIN FAKULTAS KEDOKTERAN



KOMITE ETIK PENELITIAN KESEHATAN

RSPTN UNIVERSITAS HASANUDDIN

RSUP Dr. WAHIDIN SUDIROHUSODO MAKASSAR

Sekretariat : Lantai 2 Gedung Laboratorium Terpadu

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REKOMENDASI PERSETUJUAN ETIK

Nomor : 655/UN4.6.4.5.31/ PP36/ 2021

Tanggal: 14 Oktober 2021

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

No Protokol	UH21090632	No Sponsor Protokol	
Peneliti Utama	dr. Hasan Nyambe, M.Med, Ed	Sponsor	
Judul Peneliti	PERBANDINGAN KESINTASAN PASIEN KANKER PARU KELOMPOK BUKAN SEL KECIL YANG MENDAPAT TERAPI TARGET EPIDERMAL GROWTH FACTOR RECEPTOR-TYROSIN KINASE INHIBITOR DAN YANG MENDAPAT KEMOTERAPI LINI PERTAMA		
No Versi Protokol	1	Tanggal Versi	12 Oktober 2021
No Versi PSP		Tanggal Versi	
Tempat Penelitian	RS Dr. Wahidin Sudirohusodo Makassar		
Jenis Review	<input checked="" type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal	Masa Berlaku 14 Oktober 2021 sampai 14 Oktober 2022	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 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

Lampiran 2 : karakteristik subjek penelitian

Suku

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Bugis	91	38.1	38.1	38.1
	Toraja	25	10.5	10.5	48.5
	Makassar	74	31.0	31.0	79.5
	Lain-lain	45	18.8	18.8	98.3
	Mandar	4	1.7	1.7	100.0
	Total	239	100.0	100.0	

Kelompok Umur

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	<= 40 tahun	17	7.1	7.1	7.1
	> 40 tahun	222	92.9	92.9	100.0
	Total	239	100.0	100.0	

Merokok

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Merokok	152	63.6	63.6	63.6
	Tidak merokok	87	36.4	36.4	100.0
	Total	239	100.0	100.0	

Indeks Brinkman

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Tidak Merokok	81	33.9	35.4	35.4
	Ringan	33	13.8	14.4	49.8
	Sedang	55	23.0	24.0	73.8
	Berat	60	25.1	26.2	100.0
	Total	229	95.8	100.0	
Missing	System	10	4.2		
	Total	239	100.0		

Stage

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	II B	1	.4	.4	.4
	III A	11	4.6	4.6	5.0
	III B	11	4.6	4.6	9.6
	III C	9	3.8	3.8	13.4
	IV A	181	75.7	75.7	89.1
	IV B	26	10.9	10.9	100.0
	Total	239	100.0	100.0	

Jenis Terapi

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Gefitinib	78	32.6	32.6	32.6
	Erlotinib	20	8.4	8.4	41.0
	Afatinib	6	2.5	2.5	43.5
	Karboplatin dan Vinorelbine	81	33.9	33.9	77.4
	Karboplatin dan Etoposide	3	1.3	1.3	78.7
	Karboplatin dan Paklitaksel	47	19.7	19.7	98.3
	Karboplatin dan Pemetrexed	4	1.7	1.7	100.0
Total		239	100.0	100.0	

Terapi

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Target Terapi	104	43.5	43.5	43.5
	Kemoterapi	135	56.5	56.5	100.0
	Total	239	100.0	100.0	

Survival

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Meninggal	181	75.7	75.7	75.7
	Hidup	58	24.3	24.3	100.0
	Total	239	100.0	100.0	

Lampiran 3 : Median survival 6 bulan

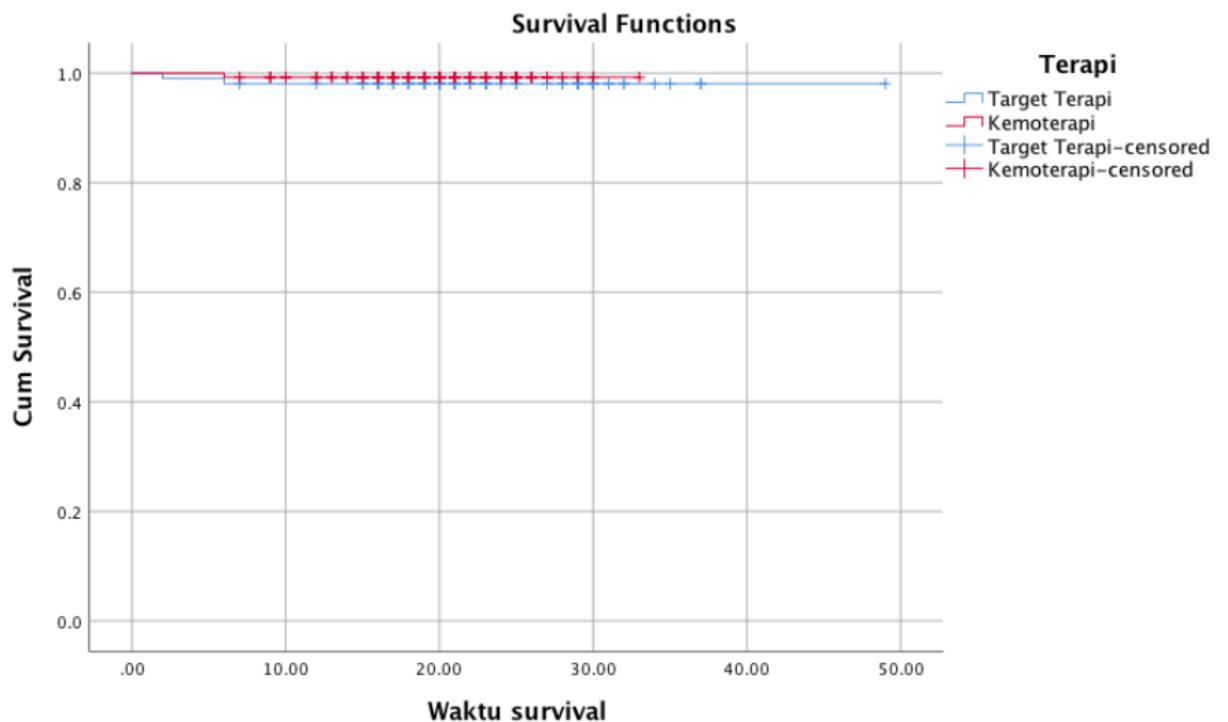
Means and Medians for Survival Time

Terapi	Estimat e	Std. Error	Mean ^a		Estimat e	Std. Error	Median		95% Confidence Interval			
			95% Confidence Interval				Lower Bound	Upper Bound				
			Lower Bound	Upper Bound								
Target Terapi	48.135	.607	46.946	49.324				
Kemoterapi	32.800	.199	32.409	33.191				
Overall	48.444	.320	47.817	49.070				

Overall Comparisons

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	.666	1	.415

The vector of trend weights is -1, 1. This is the default.



lampiran 4 :survival 12 bulan

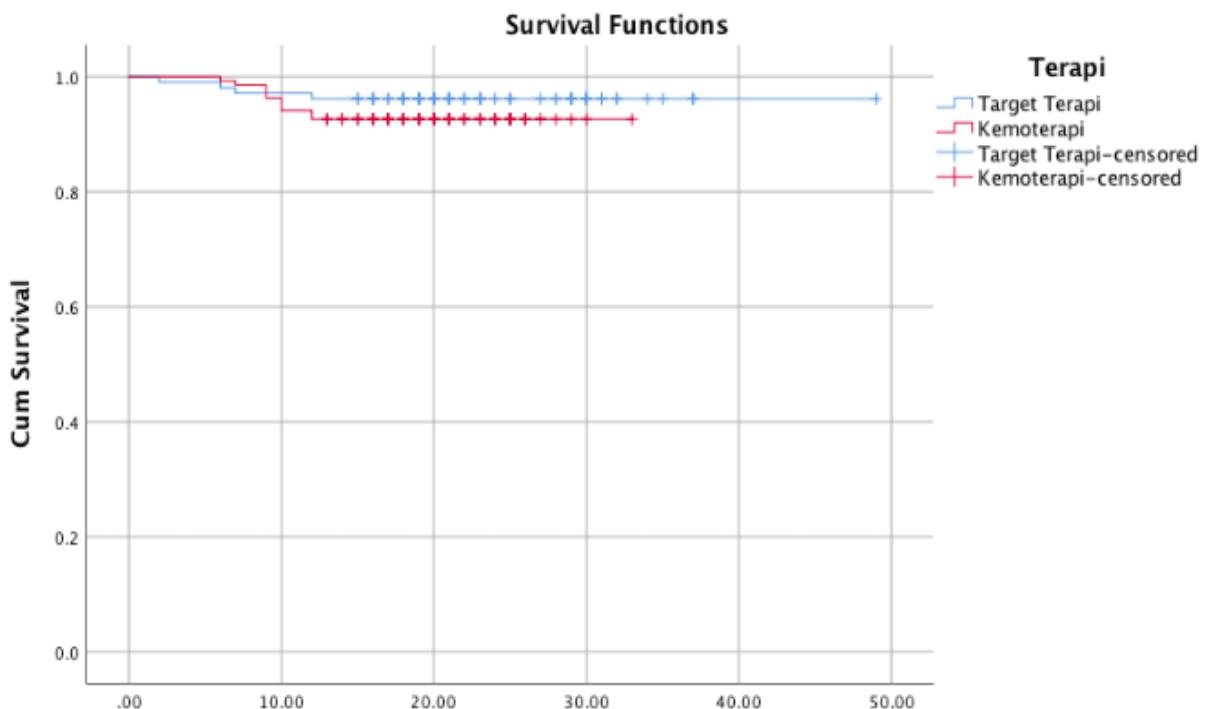
Means and Medians for Survival Time

Terapi	Mean ^a				Median			
			95% Confidence Interval				95% Confidence Interval	
	Estimate	Std. Error	Lower Bound	Upper Bound	Estimate	Std. Error	Lower Bound	Upper Bound
Target Terapi	47.375	.800	45.808	48.942
Kemoterapi	31.252	.534	30.206	32.298
Overall	46.636	.614	45.432	47.840

Overall Comparisons

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	1.291	1	.256

The vector of trend weights is -1, 1. This is the default.



Lampiran 5 : survival 24 bulan (2 tahun)

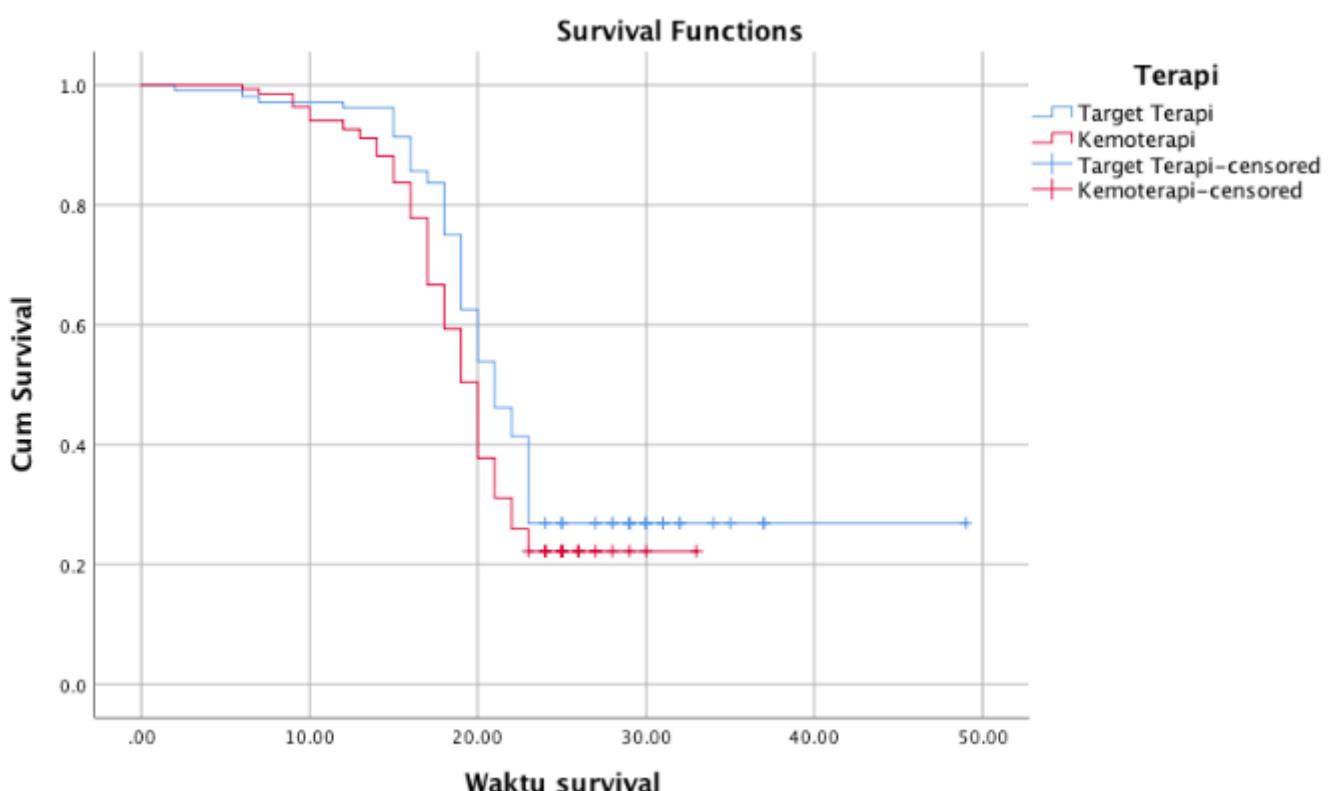
Means and Medians for Survival Time

Terapi	Mean ^a				Median			
			95% Confidence Interval				95% Confidence Interval	
	Estimate	Std. Error	Lower Bound	Upper Bound	Estimate	Std. Error	Lower Bound	Upper Bound
Target Terapi	27.077	1.344	24.442	29.712	21.000	.693	19.641	
Kemoterapi	21.074	.613	19.872	22.277	20.000	.388	19.239	
Overall	25.695	.879	23.971	27.418	20.000	.296	19.420	

Overall Comparisons

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	4.101	1	.043

The vector of trend weights is -1, 1. This is the default.



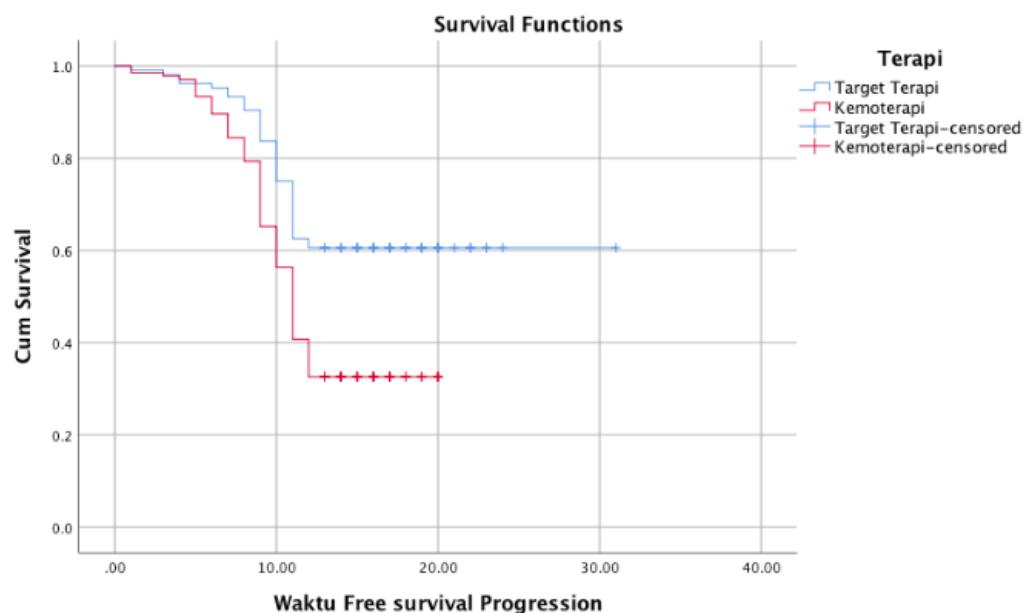
Lampiran 6 : Median PFS 12 bulan

Terapi	Mean ^a					Median		
			95% Confidence Interval				95%	
	Estimate	Std. Error	Lower Bound	Upper Bound	Estimate	Std. Error	Confidence Interval	
Target Terapi	22.394	1.057	20.323	24.466
Kemoterapi	12.615	.475	11.685	13.545	11.000	.272	10.467	
Overall	18.895	.715	17.495	20.296	12.000	.327	11.359	

Overall Comparisons

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	17.944	1	.000

The vector of trend weights is -1, 1. This is the default.



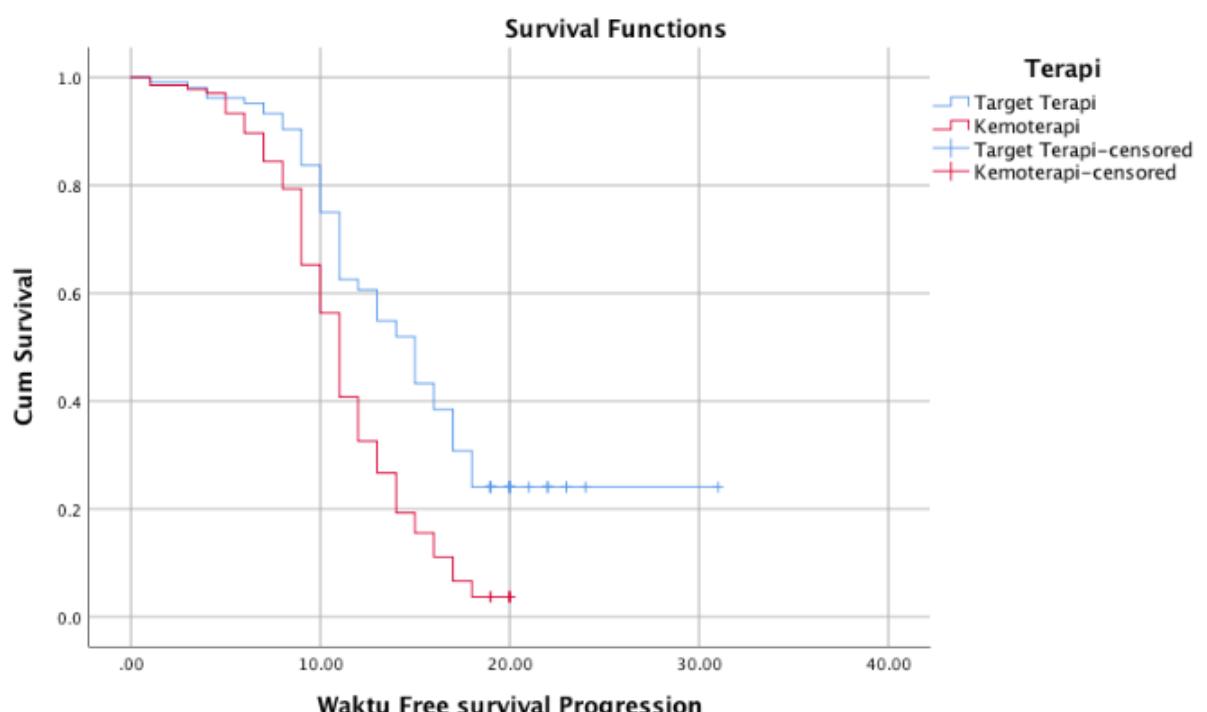
Lampiran 7: median PFS 18 bulan

Terapi	Mean ^a				Median			
	Estimate	Std. Error	95% Confidence Interval		Estimate	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound			Lower Bound	Upper Bound
Target Terapi	16.808	.851	15.140	18.475	15.000	.842	13.349	
Kemoterapi	11.200	.336	10.542	11.858	11.000	.272	10.467	
Overall	13.870	.477	12.934	14.806	12.000	.327	11.359	

Overall Comparisons

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	31.564	1	.000

The vector of trend weights is -1, 1. This is the default.



Lampiran 8 : survival berdasarkan karakteristik umur

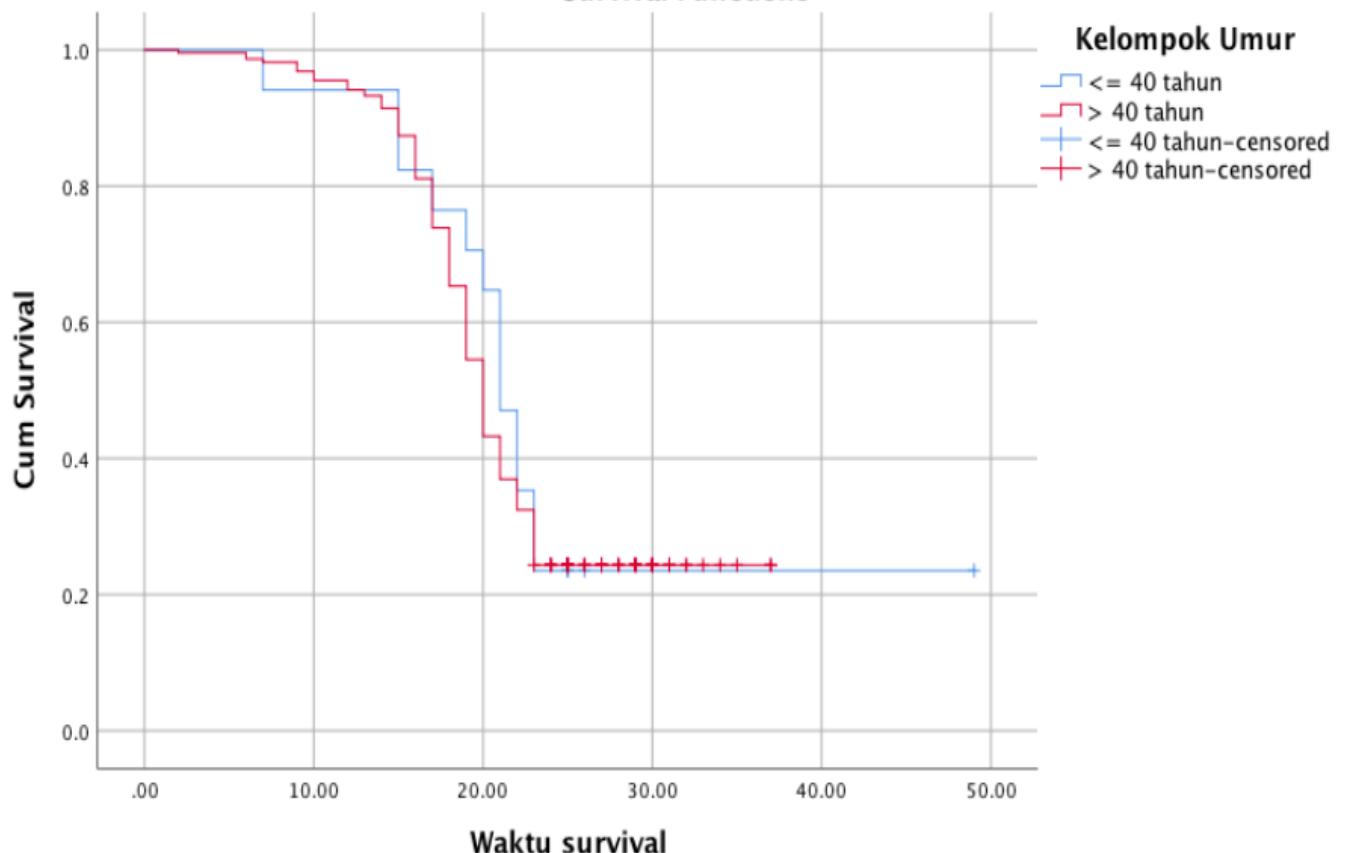
Means and Medians for Survival Time

Kelompok Umur	Mean ^a					Median		
			95% Confidence Interval				95% Confidence Interval	
	Estimate	Std. Error	Lower Bound	Upper Bound	Estimate	Std. Error	Lower Bound	
<= 40 tahun	26.000	3.227	19.675	32.325	21.000	.823	19.387	
> 40 tahun	22.752	.584	21.607	23.897	20.000	.301	19.409	
Overall	25.695	.879	23.971	27.418	20.000	.296	19.420	

Overall Comparisons

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	.203	1	.653

Survival Functions



Lampiran 9 : survival berdasarkan karakteristik Suku

Means and Medians for Survival Time

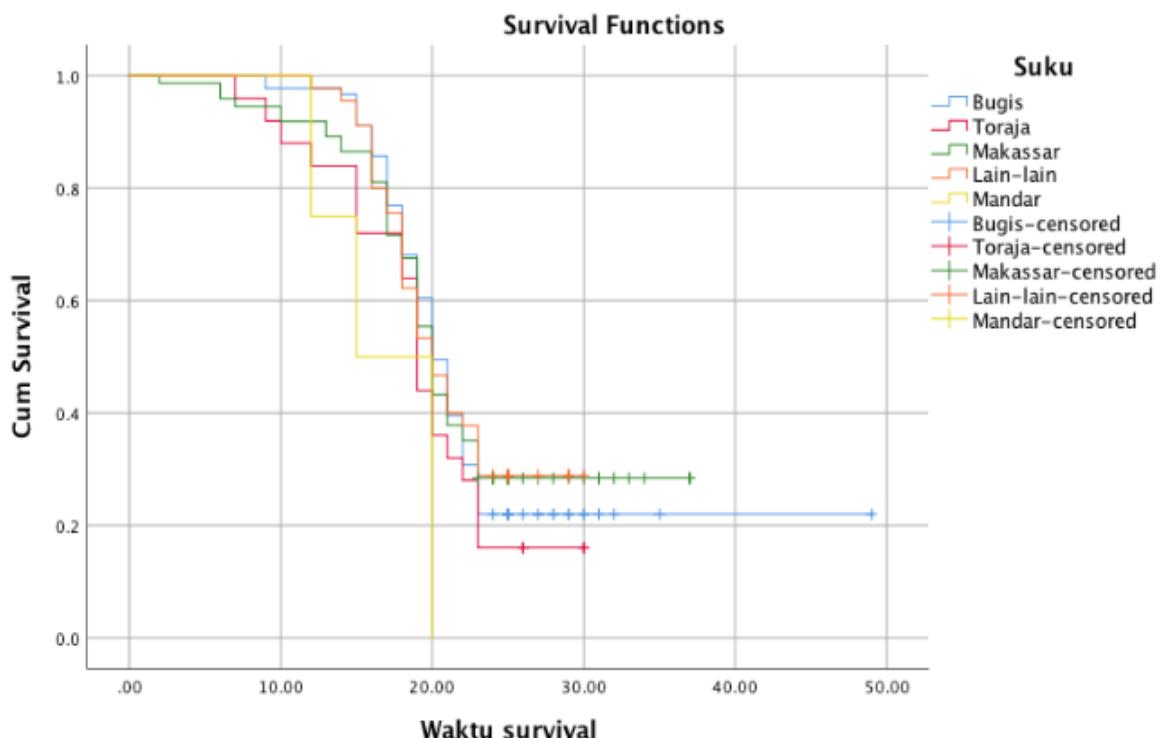
Suku	Estimate	Std. Error	Mean ^a		Estimate	Std. Error	Median	
			Lower Bound	Upper Bound			Lower Bound	Upper Bound
Bugis	25.593	1.331	22.984	28.203	20.000	.502	19.016	20.984
Toraja	19.440	1.243	17.003	21.877	19.000	.496	18.027	19.973
Makassar	23.014	1.119	20.820	25.207	20.000	.474	19.072	20.928
Lain-lain	21.800	.853	20.128	23.472	20.000	1.004	18.032	21.968
Mandar	16.750	1.974	12.881	20.619	15.000	2.667	9.773	20.227
Overall	25.695	.879	23.971	27.418	20.000	.296	19.420	20.580

a. Estimation is limited to the largest survival time if it is censored.

Overall Comparisons

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	.003	1	.958

The vector of trend weights is -2, -1, 0, 1, 2. This is the default.



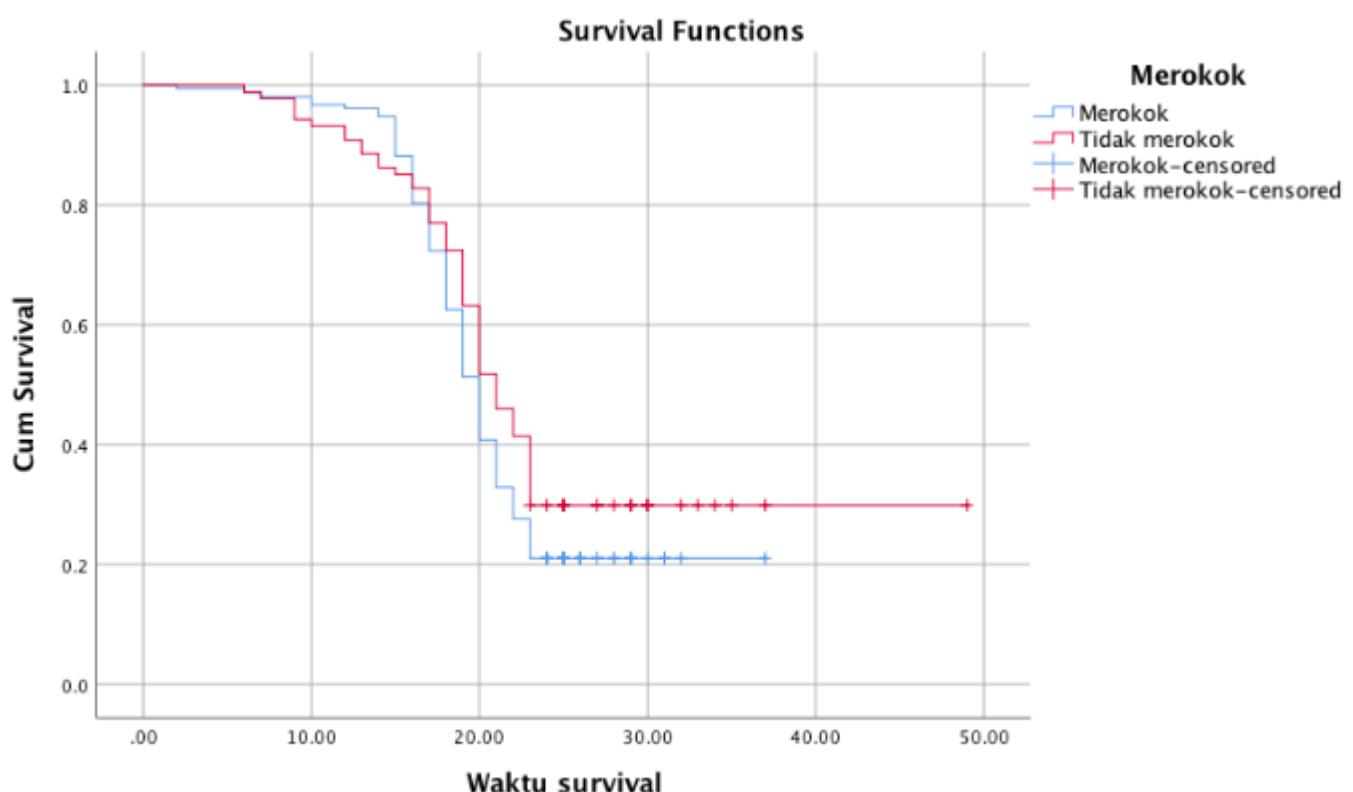
Lampiran 10 : survival berdasarkan karakteristik Status merokok

Means and Medians for Survival Time

Merokok	Mean ^a				Median			
			95% Confidence Interval				95% Confidence Interval	
	Estimat e	Std. Error	Lower Bound	Upper Bound	Estimat e	Std. Error	Lower Bound	Upper Bound
Merokok	22.211	.667	20.902	23.519	20.000	.367	19.280	
Tidak merokok	27.368	1.564	24.303	30.433	21.000	.734	19.561	
Overall	25.695	.879	23.971	27.418	20.000	.296	19.420	

Overall Comparisons

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	3.107	1	.078



Lampiran 11 : survival berdasarkan karakteristik Indeks Brinkman

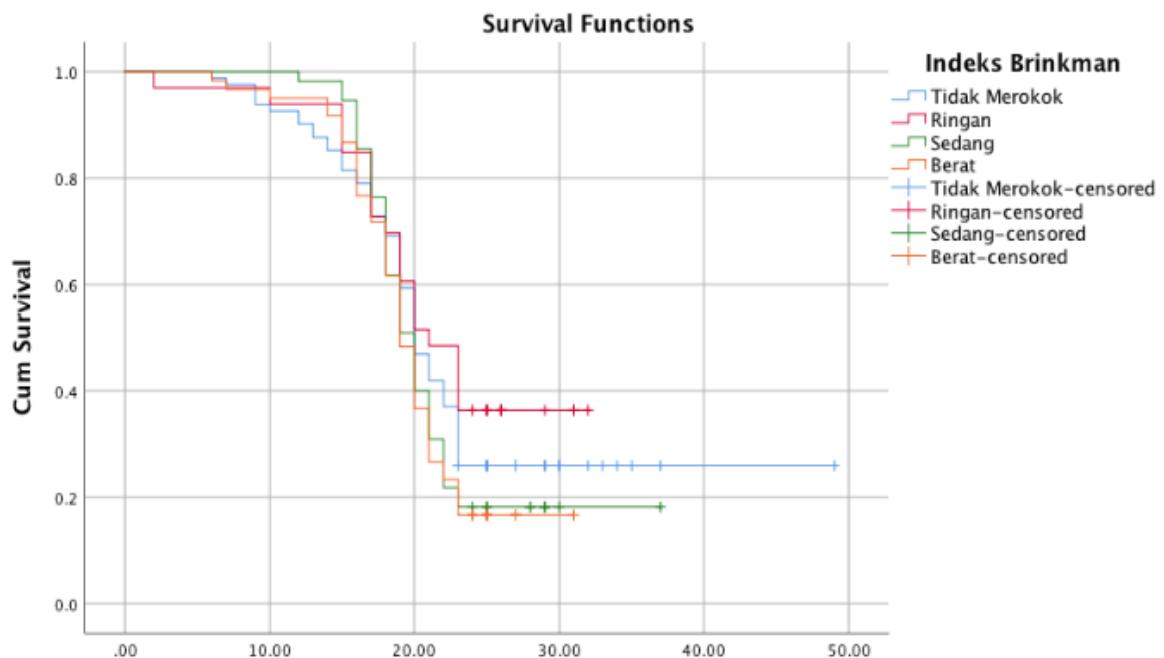
Means and Medians for Survival Time

Indeks Brinkman	Estimate	Std. Error	Mean ^a		Estimate	Std. Error	Median			
			95% Confidence Interval				95% Confidence Interval			
			Lower Bound	Upper Bound			Lower Bound	Upper Bound		
Tidak Merokok	25.975	1.570	22.899	29.052	20.000	.642	18.742			
Ringan	22.939	1.363	20.269	25.610	21.000	1.435	18.186			
Sedang	22.109	.990	20.169	24.050	20.000	.606	18.813			
Berat	20.250	.750	18.781	21.719	19.000	.516	17.988			
Overall	25.310	.887	23.572	27.048	20.000	.294	19.424			

Overall Comparisons

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	2.966	1	.085

The vector of trend weights is -3, -1, 1, 3. This is the default.



Lampiran 12 : survival berdasarkan karakteristik jenis kelamin

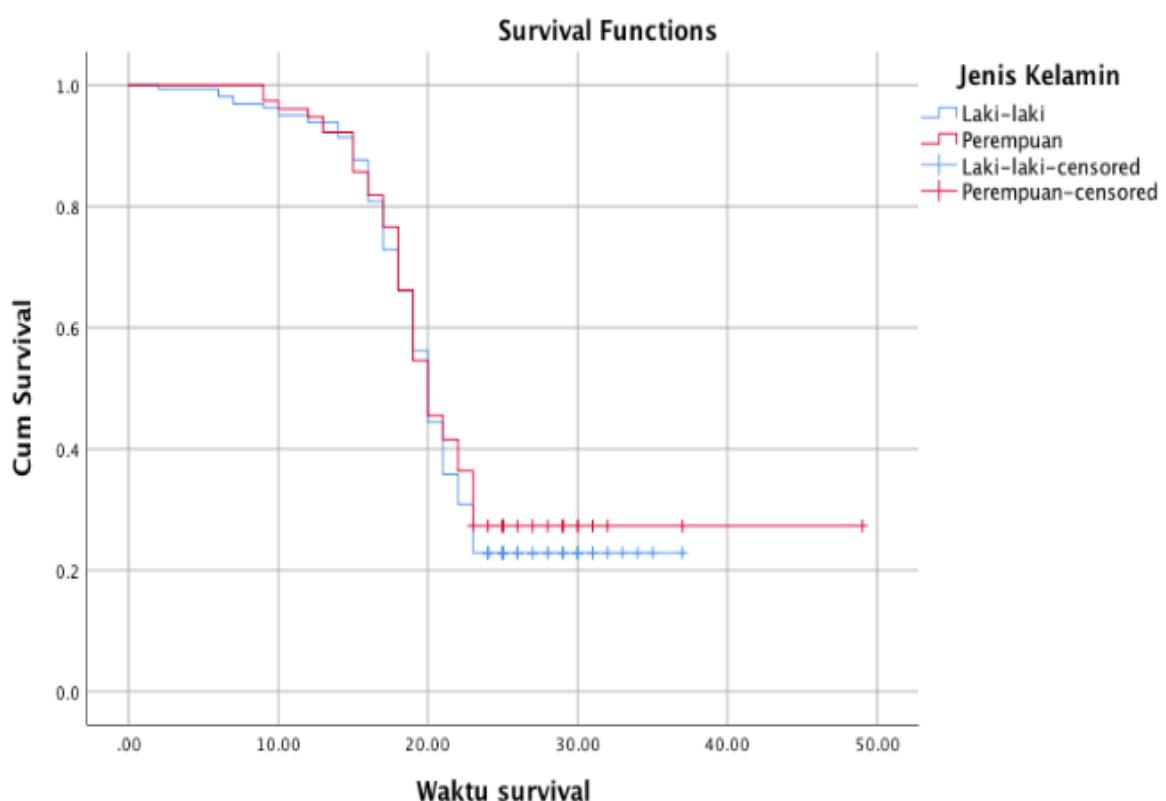
Means and Medians for Survival Time

Jenis Kelamin	Mean ^a				Median			
	Estimat e	Std. Error	95% Confidence Interval		Estimat e	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound			Lower Bound	Upper Bound
Laki-laki	22.494	.676	21.169	23.819	20.000	.333	19.348	
Perempuan	26.662	1.595	23.537	29.788	20.000	.690	18.648	
Overall	25.695	.879	23.971	27.418	20.000	.296	19.420	

Overall Comparisons

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	.377	1	.539

The vector of trend weights is -1, 1. This is the default.



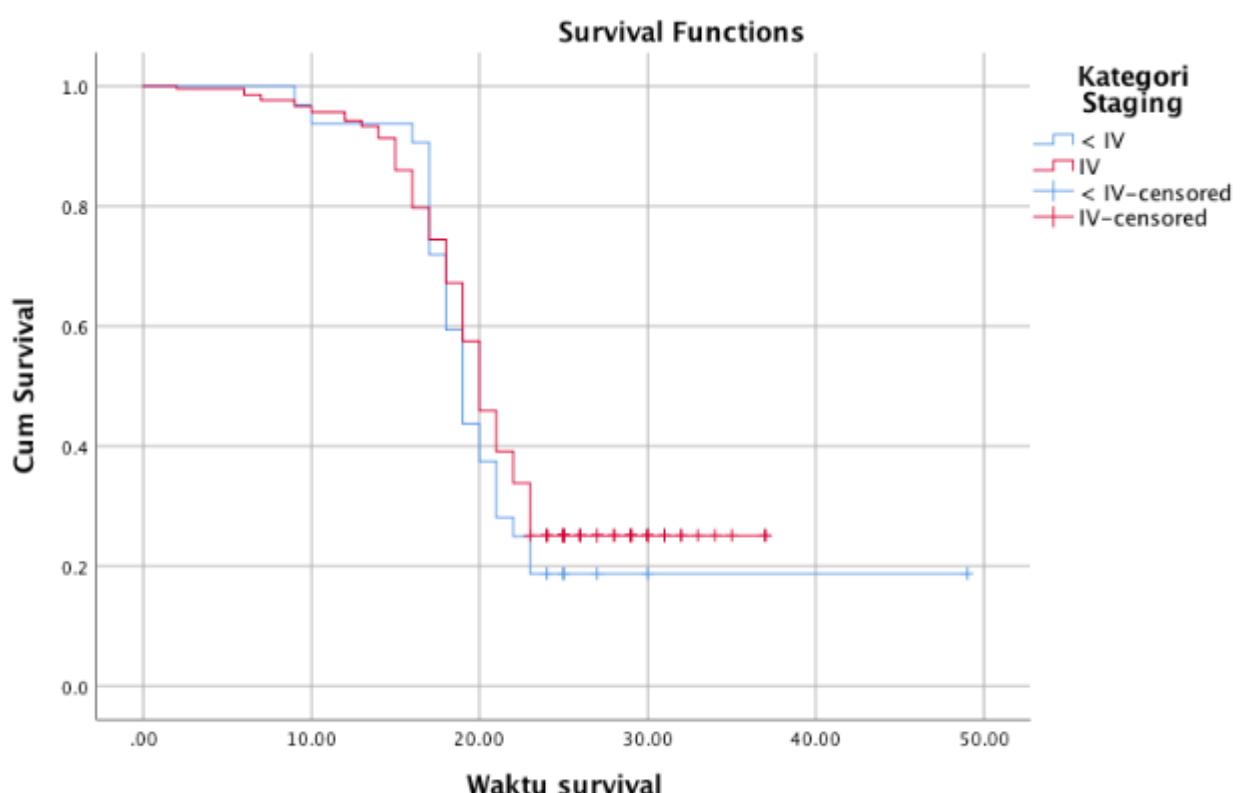
Lampiran 13 : survival berdasarkan stage

Means and Medians for Survival Time

Kategori Staging	Mean ^a					Median	95% Confidence Interval
			95% Confidence Interval		Estimat e		
	Estimat e	Std. Error	Lower Bound	Upper Bound	Std. Error	Lower Bound	
< IV	24.031	2.179	19.760	28.303	19.000	.561	17.900
IV	22.937	.612	21.737	24.137	20.000	.377	19.260
Overall	25.695	.879	23.971	27.418	20.000	.296	19.420

Overall Comparisons

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	.880	1	.348

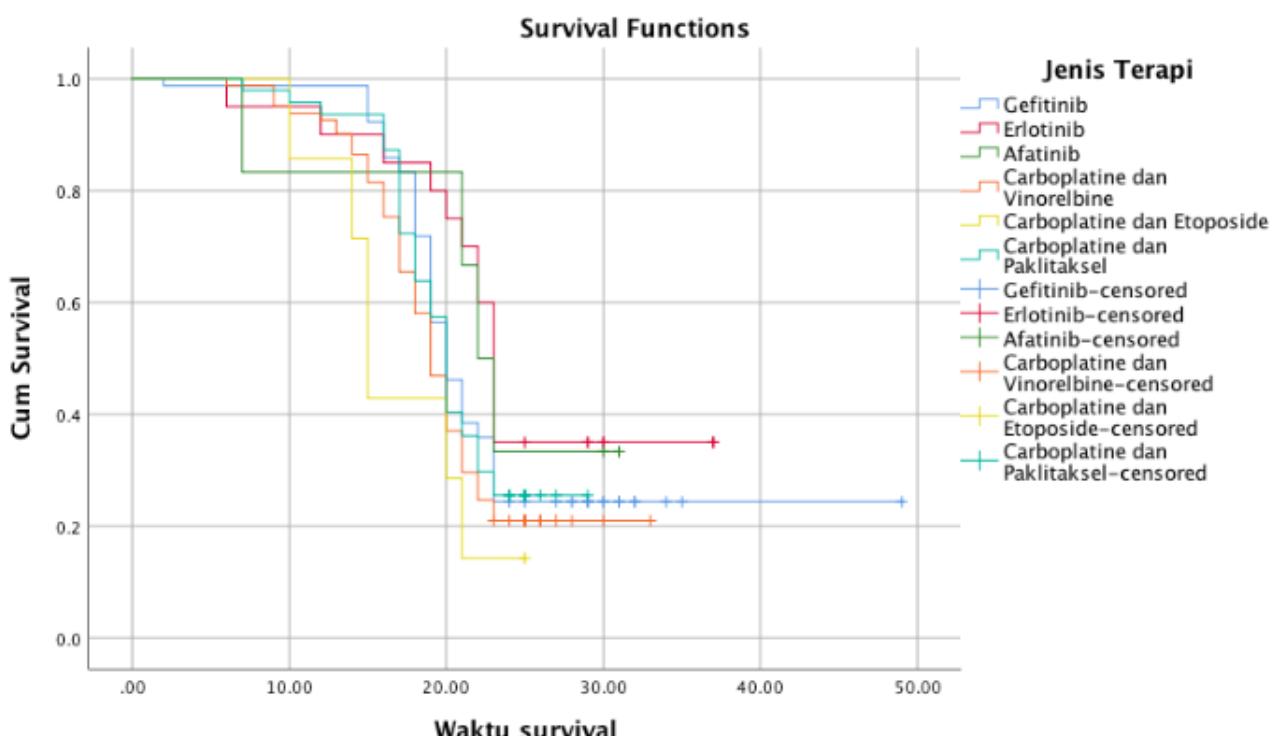


Lampiran 14 : survival berdasarkan jenis terapi keseluruhan

Jenis Terapi	Means and Medians for Survival Time							
	Mean ^a				Median			
	Estimate	Std. Error	Lower Bound	Upper Bound	Estimate	Std. Error	95% Confidence Interval	95% Confidence Interval
Gefitinib	26.269	1.495	23.338	29.200	20.000	.629	18.767	
Erlotinib	25.600	2.078	21.528	29.672	23.000	.427	22.164	
Afatinib	22.500	3.281	16.070	28.930	22.000	1.225	19.600	
Carboplatine dan Vinorelbine	20.765	.789	19.218	22.313	19.000	.528	17.964	
Carboplatine dan Etoposide	17.143	1.778	13.658	20.627	15.000	.655	13.717	
Carboplatine dan Paklitaksel	21.000	.802	19.429	22.571	20.000	.421	19.176	
Overall	25.695	.879	23.971	27.418	20.000	.296	19.420	

Overall Comparisons

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	1.500	1	.221



Lampiran 15 : survival berdasarkan indeks brinkman

Indeks Brinkman	Means and Medians for Survival Time				Median	95% Confidence Interval	Lower Bound			
	Mean ^a		95% Confidence Interval							
	Estimate	Std. Error	Lower Bound	Upper Bound						
Ringan	22.939	1.363	20.269	25.610	21.000	1.435	18.186			
Sedang	22.109	.990	20.169	24.050	20.000	.606	18.813			
Berat	20.250	.750	18.781	21.719	19.000	.516	17.988			
Overall	22.351	.681	21.017	23.685	20.000	.363	19.289			

Overall Comparisons

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	3.592	1	.058

