Time to Event Analysis: Efficacy Endpoints

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Duration Of Confirmed Response: – Fakemethaline 50 Mg (MITT Set)

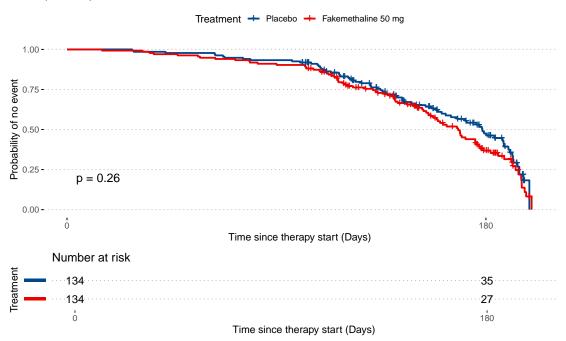


Table 1: Risk Ratio, Odds Ratio, and Risk Difference for Duration Of Confirmed Response:- Fakemethaline 50 Mg

Treatment	N	Eligible	Evt	RR	LCL.RR	UCL.R	R OR	LCL.OI	R UCL.O	R RD	LCL.R	D UCL.RE	p.fisher
Fakemethaline	134	134	82	1.14	0.93	1.4	1.36	0.84	2.21	7.46	-4.34	19.27	0.27
50 mg Placebo	134	134	72	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

 $Table\ 2: Median\ time\ to\ Event\ and\ log\ rank\ test\ for\ Duration\ Of\ Confirmed\ Response: -\ Fakemethaline\ 50\ Mg$

Treatment	N.Pop	Median.S	LCL.S	UCL.S	Absolute Difference	p.logrank
Fakemethaline 50 mg	134	168.05	157.47	177.50	-10.44	0.26
Placebo	134	178.48	164.97	189.65	NA	NA

Table 3: Hazard Ratio for Duration Of Confirmed Response:- Fakemethaline 50 Mg $\,$

Treatment	N	Hazard Ratio	Hazard Ratio LCI	Hazard Ratio UCI	p.scoretest	Median Follow Up	Follow Up LCI	Follow Up UCI
Fakemethaline 50 mg	134	1.2	0.87	1.65	0.26	183.13	178.0	191.35
Placebo	134	NA	NA	NA	NA	182.00	174.8	190.64

Duration Of Confirmed Response:- Fakemethaline 150 Mg (MITT Set)

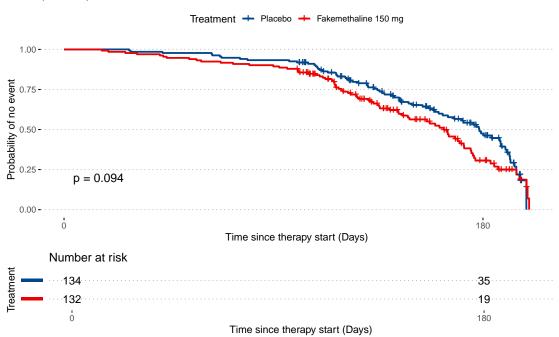


Table 4: Risk Ratio, Odds Ratio, and Risk Difference for Duration Of Confirmed Response:- Fakemethaline 150 Mg

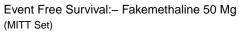
Treatment	N	Eligible	Evt	RR	LCL.RF	R UCL.R	R OR	LCL.OF	R UCL.O	R RD	LCL.R	D UCL.RI	Dp.fisher
Fakemethaline 150 mg	132	132	76	1.07	0.86	1.33	1.17	0.72	1.9	3.84	-8.09	15.78	0.54
Placebo	134	134	72	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table 5: Median time to Event and log rank test for Duration Of Confirmed Response:- Fakemethaline 150 Mg

Treatment	N.Pop	Median.S	LCL.S	UCL.S	Absolute Difference	p.logrank
Fakemethaline 150 mg	132	163.19	147.74	174.75	-15.29	0.09
Placebo	134	178.48	164.97	189.65	NA	NA

Table 6: Hazard Ratio for Duration Of Confirmed Response:- Fakemethaline 150 Mg

Treatment	N	Hazard Ratio	Hazard Ratio LCI	Hazard Ratio UCI	p.scoretest	Median Follow Up	Follow Up LCI	Follow Up UCI
Fakemethaline 150 mg	132	1.32	0.95	1.83	0.09	170.73	155.15	187.88
Placebo	134	NA	NA	NA	NA	182.00	174.80	190.64



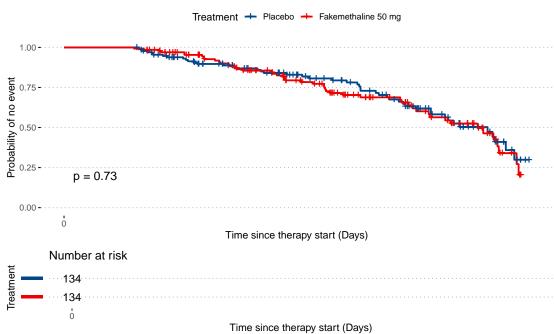


Table 7: Risk Ratio, Odds Ratio, and Risk Difference for Event Free Survival:- Fakemethaline 50 Mg

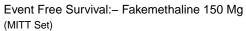
Treatment	N	Eligible	Evt	RR	LCL.RF	R UCL.R	R OR	LCL.OF	R UCL.O	R RD	LCL.RI	UCL.RD	p.fisher
Fakemethaline 50 mg	134	134	48	1.02	0.74	1.41	1.03	0.63	1.7	0.75	10.71	12.2	1
Placebo	134	134	47	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table 8: Median time to Event and log rank test for Event Free Survival:- Fakemethaline $50~\mathrm{Mg}$

Treatment	N.Pop	Median.S	LCL.S	UCL.S	Absolute Difference	p.logrank
Fakemethaline 50 mg	134	88.88	78.34	97.66	-2.12	0.73
Placebo	134	90.99	78.82	NA	NA	NA

Table 9: Hazard Ratio for Event Free Survival:- Fakemethaline 50 Mg

Treatment	N	Hazard Ratio	Hazard Ratio LCI	Hazard Ratio UCI	p.scoretest	Median Follow Up	Follow Up LCI	Follow Up UCI
Fakemethaline 50 mg	134	1.07	0.72	1.61	0.73	65.63	60.0	78.94
Placebo	134	NA	NA	NA	NA	74.14	59.7	82.50



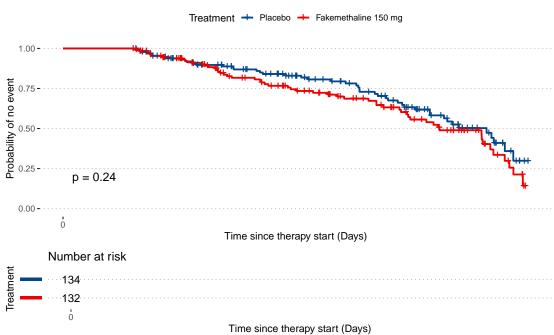


Table 10: Risk Ratio, Odds Ratio, and Risk Difference for Event Free Survival:- Fakemethaline 150 Mg

Treatment	N	Eligible	Evt	RR	LCL.RF	R UCL.R	R OR	LCL.OI	R UCL.O	R RD	LCL.R	D UCL.RI	p.fisher
Fakemethaline 150 mg	132	132	55	1.19	0.87	1.61	1.32	0.81	2.17	6.59	-5.07	18.25	0.31
Placebo	134	134	47	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table 11: Median time to Event and log rank test for Event Free Survival:- Fakemethaline 150 Mg $\,$

Treatment	N.Pop	Median.S	LCL.S	UCL.S	Absolute Difference	p.logrank
Fakemethaline 150 mg	132	80.88	73.93	94.89	-10.12	0.24
Placebo	134	90.99	78.82	NA	NA	NA

Table 12: Hazard Ratio for Event Free Survival:- Fakemethaline 150 Mg

Treatment	N	Hazard Ratio	Hazard Ratio LCI	Hazard Ratio UCI	p.scoretest	Median Follow Up	Follow Up LCI	Follow Up UCI
Fakemethaline 150 mg	132	1.26	0.86	1.87	0.24	73.67	62.34	83.91
Placebo	134	NA	NA	NA	NA	74.14	59.70	82.50

Overall Survival:- Fakemethaline 50 Mg (MITT Set)

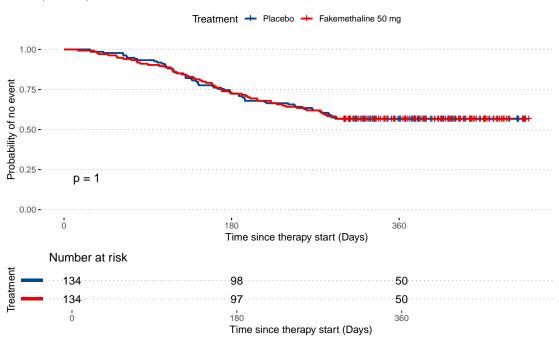


Table 13: Risk Ratio, Odds Ratio, and Risk Difference for Overall Survival:- Fakemethaline 50 Mg

Treatment	N	Eligible	Evt	RR	LCL.RR	UCL.R	R OR	LCL.OF	R UCL.O	R RD	LCL.RI	UCL.RE	p.fisher
Fakemethaline 50 mg	134	134	58	1	0.76	1.32	1	0.62	1.62	0	- 11.86	11.86	1
Placebo	134	134	58	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table 14: Median time to Event and log rank test for Overall Survival:- Fakemethaline $50~\mathrm{Mg}$

Treatment	N.Pop	Median.S	LCL.S	UCL.S	Absolute Difference	p.logrank
Fakemethaline 50 mg	134	NA	292.21	NA	NA	1
Placebo	134	NA	287.47	NA	NA	NA

Table 15: Hazard Ratio for Overall Survival:- Fakemethaline 50 Mg

Treatment	N	Hazard Ratio	Hazard Ratio LCI	Hazard Ratio UCI	p.scoretest	Median Follow Up	Follow Up LCI	Follow Up UCI
Fakemethaline 50 mg	134	1	0.69	1.44	1	398.22	369.49	425.12
Placebo	134	NA	NA	NA	NA	380.82	371.32	407.01

Overall Survival:- Fakemethaline 150 Mg (MITT Set)

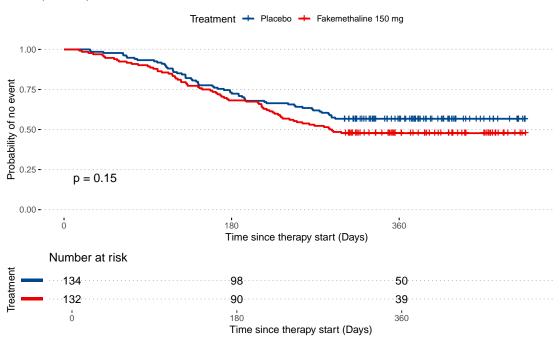


Table 16: Risk Ratio, Odds Ratio, and Risk Difference for Overall Survival:- Fakemethaline 150 Mg

Treatment	N	Eligible	Evt	RR	LCL.RF	R UCL.R	R OR	LCL.OI	R UCL.O	R RD	LCL.R	D UCL.RD	p.fisher
Fakemethaline 150 mg	132	132	69	1.21	0.94	1.56	1.44	0.89	2.33	8.99	-2.97	20.95	0.18
Placebo	134	134	58	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table 17: Median time to Event and log rank test for Overall Survival:- Fakemethaline 150 ${\rm Mg}$

Treatment	N.Pop	Median.S	LCL.S	UCL.S	Absolute Difference	p.logrank
Fakemethaline 150 mg	132	286.63	233.14	NA	NA	0.15
Placebo	134	NA	287.47	NA	NA	NA

Table 18: Hazard Ratio for Overall Survival:- Fakemethaline 150 Mg

Treatment	N	Hazard Ratio	Hazard Ratio LCI	Hazard Ratio UCI	p.scoretest	Median Follow Up	Follow Up LCI	Follow Up UCI
Fakemethaline 150 mg	132	1.29	0.91	1.83	0.15	389.27	362.16	417.74
Placebo	134	NA	NA	NA	NA	380.82	371.32	407.01

Progression Free Survival:- Fakemethaline 50 Mg (MITT Set)

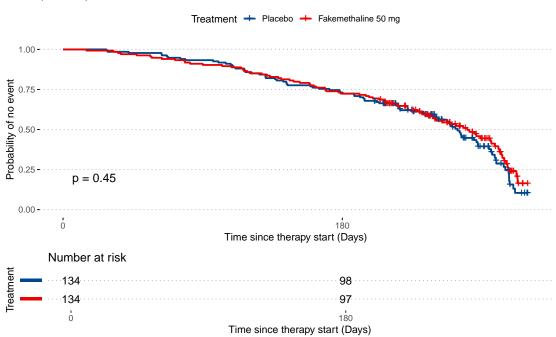


Table 19: Risk Ratio, Odds Ratio, and Risk Difference for Progression Free Survival:- Fakemethaline 50 Mg

Treatment	N	Eligible	Evt	RR	LCL.RF	R UCL.R	R OR	LCL.OF	UCL.O	R RD	LCL.RI	O UCL.RE	p.fisher
Fakemethaline	134	134	79	0.94	0.78	1.14	0.85	0.52	1.4	-	-	7.95	0.62
50 mg										3.73	15.41		
Placebo	134	134	84	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table 20: Median time to Event and log rank test for Progression Free Survival:- Fakemethaline 50 Mg

Treatment	N.Pop	Median.S	LCL.S	UCL.S	Absolute Difference	p.logrank
Fakemethaline 50 mg	134	260.59	238.40	280.61	6.36	0.45
Placebo	134	254.23	240.77	274.51	NA	NA

Table 21: Hazard Ratio for Progression Free Survival:- Fakemethaline 50 Mg

Treatment	N	Hazard Ratio	Hazard Ratio LCI	Hazard Ratio UCI	p.scoretest	Median Follow Up	Follow Up LCI	Follow Up UCI
Fakemethaline 50 mg	134	0.89	0.65	1.21	0.45	272.65	263.82	286.15
Placebo	134	NA	NA	NA	NA	271.55	259.70	287.07

Progression Free Survival:- Fakemethaline 150 Mg (MITT Set)

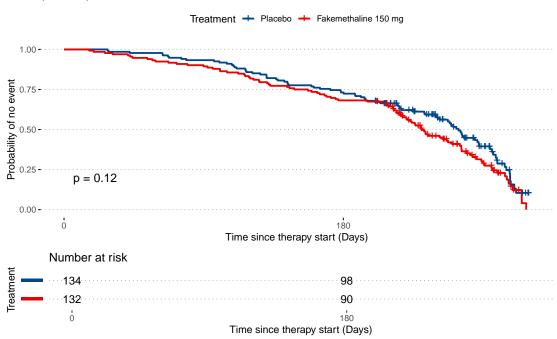


Table 22: Risk Ratio, Odds Ratio, and Risk Difference for Progression Free Survival:- Fakemethaline 150 Mg

Treatment	N	Eligible	Evt	RR	LCL.RI	R UCL.R	R OR	LCL.OI	R UCL.O	R RD	LCL.RI	O UCL.RE	p.fisher
Fakemethaline 150 mg	132	132	95	1.15	0.97	1.36	1.53	0.91	2.56	9.28	-1.93	20.5	0.12
Placebo	134	134	84	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table 23: Median time to Event and log rank test for Progression Free Survival:- Fakemethaline 150 Mg

Treatment	N.Pop	Median.S	LCL.S	UCL.S	Absolute Difference	p.logrank
Fakemethaline 150 mg	132	230.48	218.26	255.13	-23.75	0.12
Placebo	134	254.23	240.77	274.51	NA	NA

Table 24: Hazard Ratio for Progression Free Survival:- Fakemethaline 150 Mg $\,$

Treatment	N	Hazard Ratio	Hazard Ratio LCI	Hazard Ratio UCI	p.scoretest	Median Follow Up	Follow Up LCI	Follow Up UCI
Fakemethaline 150 mg	132	1.26	0.94	1.69	0.12	276.89	263.03	289.90
Placebo	134	NA	NA	NA	NA	271.55	259.70	287.07

Total Number Of Exacerbations:- Fakemethaline 50 Mg (MITT Set)

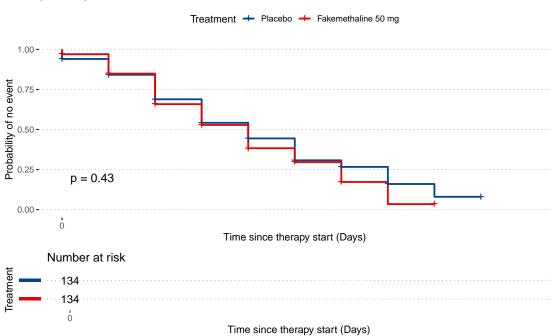


Table 25: Risk Ratio, Odds Ratio, and Risk Difference for Total Number Of Exacerbations:- Fakemethaline 50 Mg

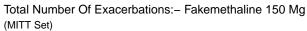
Treatment	N	Eligible	Evt	RR	LCL.RR	UCL.R	R OR	LCL.OI	R UCL.O	R RD	LCL.R	D UCL.RE	p.fisher
Fakemethaline	134	134	82	1.14	0.93	1.4	1.36	0.84	2.21	7.46	-4.34	19.27	0.27
50 mg Placebo	134	134	72	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table 26: Median time to Event and log rank test for Total Number Of Exacerbations:- Fakemethaline 50 Mg

Treatment	N.Pop	Median.S	LCL.S	UCL.S	Absolute Difference	p.logrank
Fakemethaline 50 mg	134	4	3	4	0	0.43
Placebo	134	4	3	5	NA	NA

Table 27: Hazard Ratio for Total Number Of Exacerbations:- Fakemethaline 50 Mg

Treatment	N	Hazard Ratio	Hazard Ratio LCI	Hazard Ratio UCI	p.scoretest	Median Follow Up	Follow Up LCI	Follow Up UCI
Fakemethaline 50 mg	134	1.15	0.84	1.58	0.38	5	4	NA
Placebo	134	NA	NA	NA	NA	5	4	6



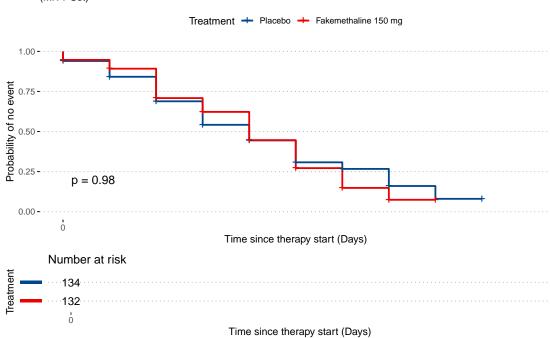


Table 28: Risk Ratio, Odds Ratio, and Risk Difference for Total Number Of Exacerbations:- Fakemethaline 150 Mg

Treatment	N	Eligible	Evt	RR	LCL.RI	R UCL.R	R OR	LCL.OF	UCL.O	R RD	LCL.R	D UCL.RE	p.fisher
Fakemethaline 150 mg	132	132	76	1.07	0.86	1.33	1.17	0.72	1.9	3.84	-8.09	15.78	0.54
Placebo	134	134	72	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table 29: Median time to Event and log rank test for Total Number Of Exacerbations:- Fakemethaline 150 Mg

Treatment	N.Pop	Median.S	LCL.S	UCL.S	Absolute Difference	p.logrank
Fakemethaline 150 mg	132	4	4	5	0	0.98
Placebo	134	4	3	5	NA	NA

Table 30: Hazard Ratio for Total Number Of Exacerbations:- Fakemethaline 150 Mg $\,$

Treatment	N	Hazard Ratio	Hazard Ratio LCI	Hazard Ratio UCI	p.scoretest	Median Follow Up	Follow Up LCI	Follow Up UCI
Fakemethaline 150 mg	132	1.02	0.74	1.41	0.91	4	4	NA
Placebo	134	NA	NA	NA	NA	5	4	6