

Secondary endpoint: % of patients with improvement of health-related QoL score as revealed by SNOT-22 by at least ten score points after 4 and 7 days of full dosage

Impact of treatment has been evaluated with SNOT-22 change score, the difference between pretreatment and post-treatment score. After 4 days of full medication dose the SNOT-22 score dropped by 22,3906 score points in the Tavipec group and by 15,9839 score points in the placebo group, thus to a greater extent in patients treated with Tavipec. After 7 days of full medication dose the SNOT-22 reduction measured 37,0917 score points in the Tavipec and 27,5304 in the placebo group (Figure 01).

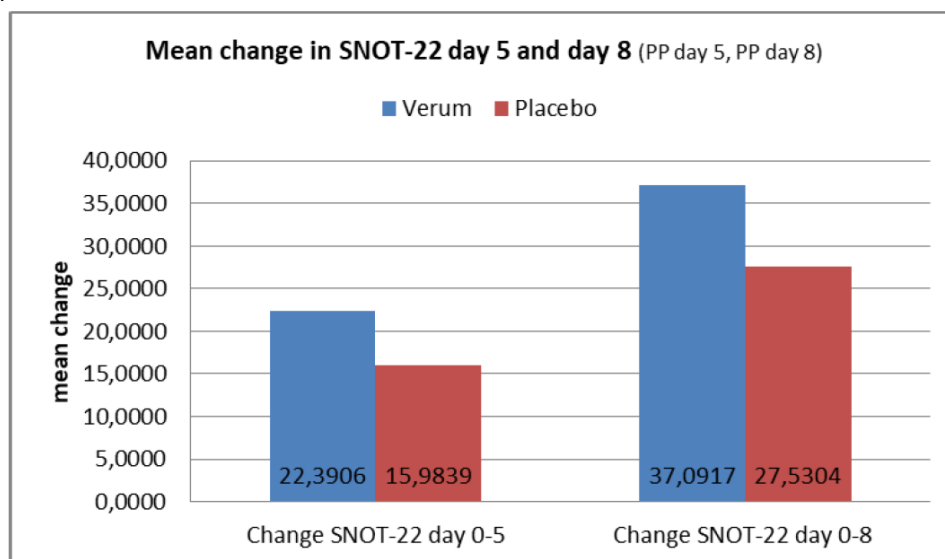


Figure 01: Mean change in SNOT-22 (PP day 5, PP day 8)

Table 01: Results for SNOT-22 day 0, day 5 and day 8 (PP day 5)

	Tavipec			Placebo			Total		
	day 0	day 5	day 8	day 0	day 5	day 8	day 0	day 5	day 8
N	128	128	121	124	124	115	252	252	236
Minimum	16,00	2,00	0,00	16,00	0,00	0,00	16,00	0,00	0,00
Maximum	91,00	71,00	87,00	97,00	85,00	60,00	97,00	85,00	87,00
Range	75,00	69,00	87,00	81,00	85,00	60,00	81,00	85,00	87,00
Mean	46,6641	24,2734	9,8595	43,5323	27,5484	15,0261	45,1230	25,8849	12,3771
Median	47,0000	22,0000	6,0000	43,0000	20,0000	10,0000	45,0000	21,0000	7,0000
SD	19,05495	15,12141	12,33782	19,05722	18,90126	14,48378	19,08267	17,13058	13,64527

Table 02: Results for SNOT-22 day 0, day 5 and day 8 (PP day 8)

	Tavipec			Placebo			Total		
	day 0	day 5	day 8	day 0	day 5	day 8	day 0	day 5	day 8
N	122	122	120	115	115	115	237	237	235
Minimum	16,00	2,00	0,00	16,00	0,00	0,00	16,00	0,00	0,00
Maximum	91,00	68,00	87,00	97,00	80,00	60,00	97,00	80,00	87,00
Range	75,00	66,00	87,00	81,00	80,00	60,00	81,00	80,00	87,00
Mean	46,2869	23,4590	9,4917	42,5565	25,9739	15,0261	44,4768	24,6793	12,2000
Median	47,0000	21,0000	6,0000	42,0000	20,0000	10,0000	44,0000	20,0000	7,0000
SD	19,29864	14,35048	11,70434	18,75427	17,49710	14,48378	19,08779	15,97053	13,39977

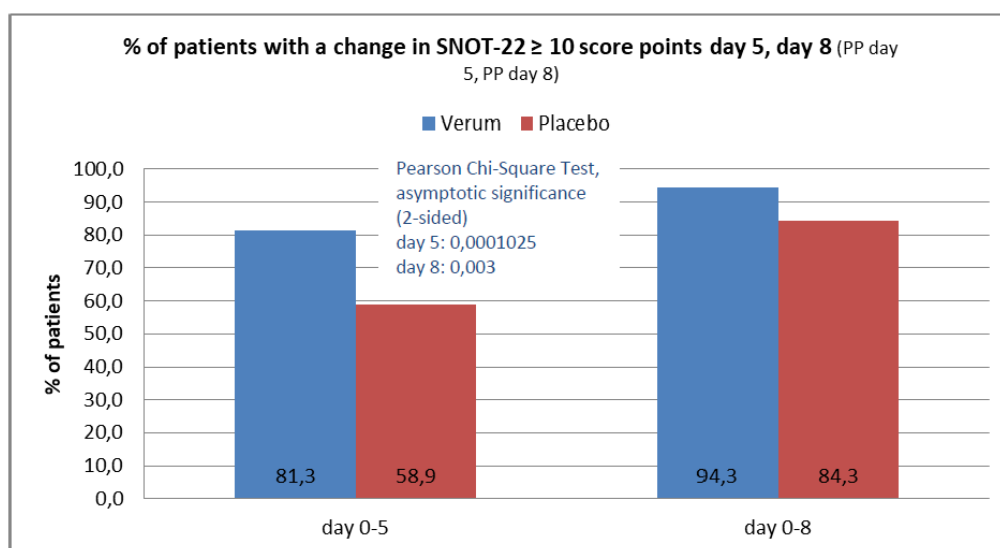
Table 03: Results for SNOT-22 changes day 0, day 5 and day 8 (PP day 5)

	Tavipec		Placebo		Total	
	change SNOT-22 day 0-5	change SNOT-22 day 0-8	change SNOT-22 day 0-5	change SNOT-22 day 0-8	change SNOT-22 day 0-5	change SNOT-22 day 0-8
N	128	121	124	115	252	236
Minimum	-14,00	-16,00	-36,00	0,00	-36,00	-16,00
Maximum	87,00	90,00	67,00	91,00	87,00	91,00
Range	101,00	106,00	103,00	91,00	123,00	107,00
Mean	22,3906	36,8678	15,9839	27,5304	19,2381	32,3178
Median	21,0000	37,0000	14,0000	26,0000	18,5000	31,0000
SD	15,76562	19,19286	15,92665	18,26286	16,13584	19,28147

Table 04: Results for SNOT-22 changes day 0, day 5 and day 8 (PP day 8)

	Tavipec		Placebo		Total	
	change SNOT-22 day 0-5	change SNOT-22 day 0-8	change SNOT-22 day 0-5	change SNOT-22 day 0-8	change SNOT-22 day 0-5	change SNOT-22 day 0-8
N	122	120	115	115	237	235
Minimum	-14,00	-16,00	-36,00	0,00	-36,00	-16,00
Maximum	87,00	90,00	67,00	91,00	87,00	91,00
Range	101,00	106,00	103,00	91,00	123,00	107,00
Mean	22,8279	37,0917	16,5826	27,5304	19,7975	32,4128
Median	21,5000	37,5000	14,0000	26,0000	19,0000	31,0000
SD	15,73158	19,11399	15,69835	18,26286	15,99103	19,26723

After 4 days of treatment 81,3 % of patients in the Tavipec group compared to only 58,9% of patients in the placebo group reported a change in SNOT-22 ≥ 10 score points and hence an improvement of their symptoms. The Chi-Square test shows a significance level of 0,0001025. Therefore it can be concluded that the proportion of subjects with a change in SNOT-22 greater or equal 10 score points from day 0 to day 5 for the verum group is significantly higher than for the placebo group. In 94,3% of Tavipec-treated patients in contrast to 84,3% of patients under placebo treatment the SNOT-22 score decreased by greater or equal 10 score points from day 0 to day 8. Resulting in a significant higher change in SNOT-22 for the verum group than for the placebo group as confirmed with the Chi-Square test (0,003) (Figure 02).

**Figure 02: % of patients with a change in SNOT-22 ≥ 10 score points, day 0-5 and day 0-8**

TAV02-13

Results sec. endpoint: SNOT-22

Table 05: Change in SNOT-22 \geq 10 score points, day 0-5 and day 0-8 (PP day 5)

			Change in SNOT-22 day 0-5 \geq 10 score points		Change in SNOT-22 day 0-8 \geq 10 score points	
			Frequency	Percent	Frequency	Percent
TAVIPEC	valid	no	24	18,8	5	3,9
		yes	104	81,3	116	90,6
		total	128	100,0	121	94,5
	Missing	system	-	-	7	5,5
	Total		-	-	128	100,0
PLACEBO	no	yes	51	41,1	18	14,5
		yes	73	58,9	97	78,2
		total	124	100,0	115	92,7
	Missing	system	-	-	9	7,3
	Total		-	-	124	100,0

Table 06: Change in SNOT-22 \geq 10 score points, day 0-5 and day 0-8 (PP day 8)

			Change in SNOT-22 day 0-5 \geq 10 score points		Change in SNOT-22 day 0-8 \geq 10 score points	
			Frequency	Percent	Frequency	Percent
TAVIPEC	valid	no	22	18,0	5	4,1
		yes	100	82,0	115	94,3
		total	122	100,0	120	98,4
	Missing	system	-	-	2	1,6
	Total		-	-	122	100,0
PLACEBO	no	yes	46	40,0	18	15,7
		yes	69	60,0	97	84,3
		total	115	100,0	115	100,0