

Supplementary 1.

Change from baseline for vital signs by treatment groups and within-groups over 90 days of trial period.

Day	Descriptive				Change from Baseline			
	UC-II (n=50)		Placebo (n=52)		UC-II vs. Placebo ¹ (n=102)		Within-group ²	
	Mean±SD	Mean±SD	Mean (95% CI)	p-value	UC-II (n=50)	Follow-up vs. Baseline	Placebo (n=52)	p-value
Pulse rate (times/min)								
Day 1	73.96±9.48	79.75±10.48	-	-	0.50	-0.20 (-4.01; 3.61)	0.99	-4.73 (-9.35; -0.11)
Day 7	73.76±10.46	75.02±8.67	1.20 (-2.33; 4.74)	0.44	0.69	1.42 (-2.99; 5.83)	0.99	-2.46 (-6.89; 1.97)
Day 30	75.38±11.57	77.29±9.17	0.78 (-3.06; 4.62)	0.99	-0.51 (-4.12; 3.10)	-1.74 (-6.41; 2.93)	0.99	-5.10 (-9.50; -0.70)
Day 60	72.22±10.84	74.63±7.72	2.07 (-1.84; 5.98)	0.29	0.78	1.66 (-2.45; 5.77)	0.99	-3.67 (-8.58; 1.24)
Day 90	75.62±12.40	76.08±8.17	-	0.33	-	-	-	-
Systolic blood pressure (mmHg)								
Day 1	116.84±14.57	116.08±15.50	-	-	0.59	-0.94 (-6.00; 4.54)	0.99	0.65 (-4.99; 6.30)
Day 7	115.90±14.90	116.73±14.68	-1.27 (-6.00; 3.46)	0.99	0.22	-2.44 (-7.36; 2.48)	0.99	0.56 (-4.72; 5.84)
Day 30	114.40±14.20	116.63±15.17	-2.72 (-7.13; 1.69)	0.99	-0.37 (-4.65; 3.91)	0.86	-1.56 (-6.35; 3.23)	0.99
Day 60	115.28±15.40	115.17±13.34	-0.37 (-4.65; 3.91)	0.99	-0.66 (-4.97; 3.66)	0.76	-1.54 (-6.29; 3.21)	0.99
Day 90	115.30±15.86	115.48±12.84	-	0.99	-	-	-	-0.60 (-5.92; 4.73)
Diastolic blood pressure (mmHg)								
Day 1	75.38±9.34	75.06±8.22	-	-	0.98	0.22 (-3.72; 4.16)	0.99	0.33 (-3.31; 3.97)
Day 7	75.60±10.28	75.38±9.01	0.04 (-3.26; 3.33)	0.99	-1.43 (-4.28; 1.43)	0.32	-1.38 (-4.92; 2.16)	0.99
Day 30	74.00±6.99	75.29±9.10	0.23 (-2.46; 2.92)	0.99	-0.31 (-0.59; 1.21)	0.87	0.24 (-2.97; 3.45)	0.99
Day 60	75.62±9.43	75.21±7.23	0.93 (-1.92; 3.78)	0.99	-0.41 (-0.46; 1.29)	0.52	0.62 (-2.75; 3.99)	0.99
Day 90	76.00±8.81	74.90±8.25	-	-	-	-	-	-0.15 (-3.67; 3.36)
Respiratory rate (times/min)								
Day 1	18.16±1.89	18.42±2.90	-	-	0.75	-0.60 (-1.81; 0.61)	0.99	-0.94 (-2.07; 0.19)
Day 7	17.56±2.03	17.48±1.98	0.12 (-0.65; 0.89)	0.99	-0.11 (-0.92; 0.69)	0.78	-0.26 (-1.29; 0.78)	0.99
Day 30	17.90±1.93	18.00±2.21	-0.31 (-0.59; 1.21)	0.99	-0.49	-0.10 (-1.32; 1.12)	0.99	-0.64 (-1.93; 0.66)
Day 60	18.06±2.19	17.79±2.42	0.41 (-0.46; 1.29)	0.99	-0.35	0.02 (-1.03; 1.07)	0.99	-0.62 (-2.02; 0.79)
Day 90	18.18±2.08	17.81±2.38	-	-	-	-	-	-0.99 (-2.02; 0.99)
Temperature (°C)								
Day 1	36.33±0.28	36.37±0.34	-	-	-	-	-	-
Day 7	36.29±0.28	36.25±0.29	0.06 (-0.06; 0.17)	0.32	-0.04 (-0.16; 0.09)	0.99	-0.12 (-0.29; 0.05)	0.39
Day 30	36.26±0.34	36.30±0.26	-0.03 (-0.15; 0.09)	0.60	-0.07 (-0.24; 0.10)	0.99	-0.07 (-0.23; 0.09)	0.99
Day 60	36.16±0.33	36.22±0.30	-0.10 (-0.22; 0.02)	0.09	-0.17 (-0.32; -0.02)	0.02	-0.10 (-0.25; 0.05)	0.61
Day 90	36.21±0.32	36.27±0.32	-0.06 (-0.19; 0.07)	0.34	-0.13 (-0.28; 0.03)	0.23	-0.10 (-0.30; 0.09)	0.99

¹Baseline-adjusted ANCOVA within the GLM procedures for change from baseline (95% confidence interval) between UC-II vs. placebo group at individual follow-up day, significant at the level of p<0.05; ²Paired t-test for change from baseline (95% confidence interval) between UC-II vs. placebo group at individual follow-up day (7, 30, 60, or 90) vs. day 1 (baseline) in each study group, significant at the level of p<0.05.

Supplementary 2.

Contingency tables for categorical urinalysis indicators.

Parameters	UC-II (n=50)	Placebo (n=52)
Color		
Yellow	45 (92%)	51 (98.08%)
Light Yellow	4 (8%)	1 (1.92%)
Clarity		
Cloudy	3 (6%)	2 (3.85%)
Slightly cloudy	12 (24%)	13 (25.00%)
Cloudy	35 (70%)	37 (71.15%)
Blood		
Positive	24 (48%)	24 (46.15%)
Negative	26 (52%)	28 (53.85%)
Leucocyte esterase		
Positive	16 (32%)	12 (23.08%)
Negative	34 (68%)	40 (76.92%)
Nitrite		
Positive	0 (0%)	1 (1.92%)
Negative	50 (100%)	51 (98.08%)
Albumin		
Positive	2 (4%)	1 (1.92%)
Negative	48 (96%)	51 (98.08%)
Glucose		
Positive	1 (2%)	1 (1.92%)
Negative	49 (98%)	51 (98.08%)
Ketone		
Positive	1 (2%)	0 (0%)
Negative	49 (98%)	52 (100%)
Urobilinogen		
Positive	0 (0%)	0 (0%)
Normal	50 (100%)	52 (100%)
Bilirubin		
Positive	0 (0%)	0 (0%)
Negative	50 (100%)	52 (100%)
Red blood cells		
>5	7 (14%)	7 (13.16%)
0-5 (normal)	43 (86%)	45 (86.54%)
White blood cells		
>5	16 (32%)	12 (23.08%)
0-5 (normal)	34 (68%)	40 (76.92%)
Epithelial cells		
Squamosal >6 / 0-6 trans	17 (34%)	23 (44.23%)
Squamosal 0-6 (normal)	33 (66%)	29 (55.77%)
Casts		
>5	0 (0%)	0 (0%)
0-5 (normal)	50 (100%)	52 (100%)
Crystal		
Positive	10 (20%)	13 (25%)
Negative	40 (80%)	39 (75%)
Bacteria		
Positive	16 (32%)	12 (23.08%)
Negative	34 (68%)	40 (76.92%)
Yeast		
Positive	0 (0%)	0 (0%)
Negative	50 (100%)	52 (100%)