

ONLINE RESOURCE: SUPPLEMENTARY DATA

JOURNAL: Supportive Care in Cancer

TITLE: Therapeutic potential of anamorelin, a novel, oral ghrelin mimetic, in patients with cancer-related cachexia: a multicenter, randomized, double-blind, crossover, pilot study

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Online Resource Table S1 Anderson Symptom Assessment Scale (ASAS) [24, 25]

ASAS was administered to patients during screening, before study day 1, and on the final day of each study period.

Patient-reported measurement/items	Mean baseline value (n=16)	Mean change after 3 days of anamorelin treatment (n=15)	Mean change after 3 days of placebo treatment (n=16)	95% Confidence interval	<i>p</i> Value
Pain	6.69	0.13	0.31	−1.1 to 0.9	0.901
Fatigue	5.50	1.47	0.38	−0.2 to 2.1	0.116
Nausea	8.63	0.33	−0.38	0.0 to 1.7	0.076
Depression	8.25	0.93	0.50	−0.2 to 1.0	0.218
Anxiety	8.13	0.73	0.31	−0.3 to 1.3	0.267
Drowsiness	7.19	0.60	−0.50	0.2 to 1.9	0.039 ^a
Shortness of breath	7.25	0.27	−0.13	−0.7 to 1.4	0.558
Appetite	4.00	2.67	0.50	0.7 to 3.3	0.011 ^a
Sleep	4.94	0.73	0.50	−0.2 to 0.8	0.253
Feeling of well-being	5.88	0.20	−0.50	−0.1 to 1.6	0.103
ASAS total score	66.44	8.07	1.00	3.5 to 10.3	<0.002 ^a

^aStatistically significant for treatment. All statistical tests were performed as 2-tailed tests at the 0.05 level of significance unless otherwise specified. A nominal *p* value was reported without adjustment for multiplicity. Missing data were not imputed. (Please see the Statistical Analysis section under Methods in the article for complete description of statistical analysis.)

Online Resource Table S2 Functional assessment of chronic illness therapy with additional fatigue domain (FACIT-F) [26]

The FACIT-F was administered to patients during screening, before study day 1, and on the final day of each study period.

Patient-reported measurement/items	Mean baseline value (<i>n</i> =16)	Mean change after 3 days of anamorelin treatment (<i>n</i> =15)	Mean change after 3 days of placebo treatment (<i>n</i> =16)	95% Confidence interval	<i>p</i> Value
Physical well-being	16.75	4.40	2.94	−0.2 to 3.5	0.105
Social/family well-being	17.69	0.60	0.44	−1.3 to 1.4	0.920
Emotional well-being	17.56	1.40	0.94	−0.4 to 1.5	0.302
Functional well-being	14.31	0.67	−0.44	−0.6 to 2.5	0.265
Additional concerns	29.06	6.13	2.44	0.2 to 6.3	0.06
FACIT-F total score	95.38	13.20	6.31	1.8 to 11.3	0.018 ^a

^aStatistically significant for treatment. All statistical tests were performed as 2-tailed tests at the 0.05 level of significance unless otherwise specified. A nominal *p* value was reported without adjustment for multiplicity. Missing data were not imputed. (Please see the Statistical Analysis section under Methods in the article for complete description of statistical methods.)

Online Resource Table S3 Bristol-Myers Anorexia/Cachexia Recovery Instrument–7 Questions (BACRI-7) [27]

The BACRI-7 was administered on the last day of each period because it assesses subjective patient-perceived improvement in anorexia and cachexia.

Patient-reported measurement/items	Mean scores after 3 days of anamorelin treatment (<i>n</i> =15)	Mean scores after 3 days of placebo treatment (<i>n</i> =16)	95% Confidence interval	<i>p</i> Value
Since you began treatment with the test drug, do you feel that any change in weight has had a significant impact on your health?	65.00	56.44	0.6 to 15.2	0.053
To what extent has your appearance changed since treatment was started?	63.67	52.56	3.0 to 20.0	0.020 ^a
Based on comments from friends, co-workers, and loved ones, how do you feel your appearance has changed since the start of treatment?	35.47	31.56	−9.6 to 15.5	0.649
To what extent has your appetite changed since the start of treatment?	67.73	61.75	−3.7 to 16.1	0.240
Do you enjoy eating more or less than before treatment began?	65.27	57.31	0.9 to 15.9	0.046 ^a
Do you think treatment has been of benefit to you?	66.27	64.44	−7.8 to 12.1	0.675
Since beginning treatment, has your quality of life become better or worse?	62.13	59.13	−5.5 to 13.0	0.443
BACRI-7 total score	454.60	420.06	−6.7 to 81.8	0.120

^aStatistically significant for treatment. All statistical tests were performed as 2-tailed tests at the 0.05 level of significance unless otherwise specified. A nominal *p* value was reported without adjustment for multiplicity. Missing data were not imputed. (Please see the Statistical Analysis section under Methods in the article for complete description of statistical methods.)

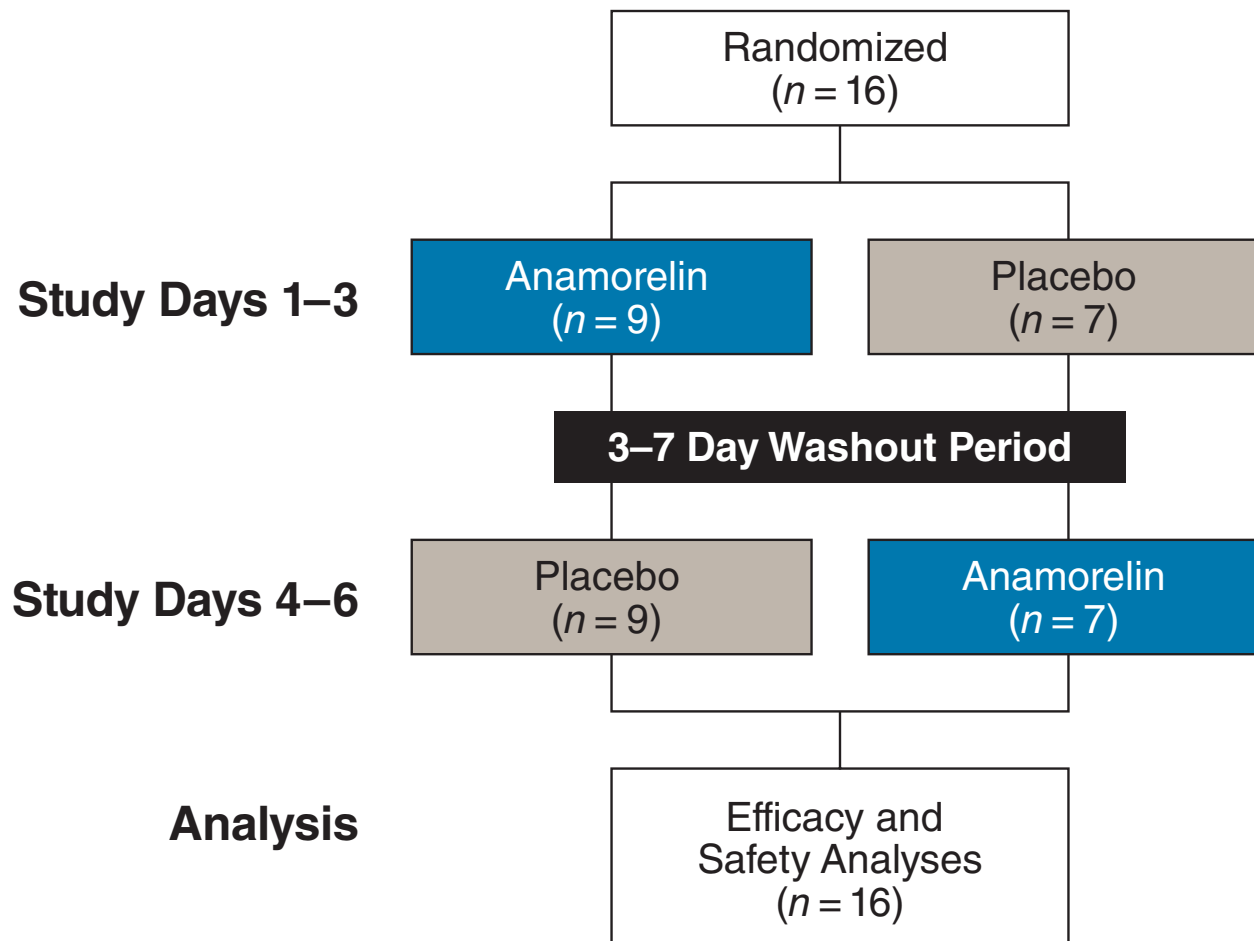


Fig. S1 Study design and patient disposition