N02C4

Phase III Double-Blind, Placebo-Controlled Randomized Comparison of Creatine for Cancer-Associated Weight Loss

ClinicalTrial.gov Identifier: NCT00081250

Study Background

Trial Description

RATIONALE: It is not yet known whether the supplement creatine is effective in increasing weight and improving appetite and quality of life in patients who have cancer. PURPOSE: This randomized phase III trial is studying how well creatine works in increasing weight and improving appetite and quality of life in patients with weight loss caused by cancer.

Arms:

Arm I: (Experimental): Patients receive oral creatine daily.

Arm II: (Placebo Comparator): Patients receive oral placebo daily.

Objectives:

- OBJECTIVES:
  - Compare weight-gain effects of creatine vs placebo in patients with cancer-associated weight loss and/or anorexia.
  - Determine the effect of these regimens on quality of life in these patients.
  - Compare the toxic effects of these regimens in these patients.
  - Compare survival rates of patients treated with these regimens.
- OUTLINE: This is a randomized, double-blind, placebo-controlled study. Patients are stratified according to primary cancer type (lung vs gastrointestinal vs other), weight loss severity (< 10 lbs vs ≥ 10 lbs), age (< 50 years vs ≥ 50 years), planned concurrent chemotherapy (yes vs no), gender, and prognosis. Patients are randomized to 1 of 2 treatment arms.
  - Arm I: Patients receive oral creatine daily.
  - Arm II: Patients receive oral placebo daily. In both arms, treatment continues in the absence of unacceptable toxicity as long as treatment is considered beneficial.
- Patients are followed every 6 months for up to 5 years.
- PROJECTED ACCRUAL: A total of 300 patients will be accrued for this study.

Study Milestones:

Start date: December 2004

Primary Completion Date: December 2007

Publication Information:

Analysis Type: Primary

Pubmed ID: 28475678

Citation: Ann Oncol. 2017 Aug 1;28(8):1957-1963. doi: 10.1093/annonc/mdx232.

Associated Datasets: NCT00081250-D1-Dataset.csv (qol), NCT00081250-D2-Dataset.csv (demo)

Dataset Information:

Dataset Name: NCT00081250-D2-Dataset.csv (demo)

Description: Dataset NCT00081250-D2-Dataset.csv (demo) is one of 2 datasets associated with PubMed ID 28475678. This dataset contains information that will allow you to reproduce the baseline characteristics table, primary analysis, and adverse event analysis.

NCT00081250-D2-Dataset.csv (demo) Data Dictionary:

- "Missing" corresponds to missing or unavailable data.

LABEL	NAME	elements	comments
Reference ID	PATREF		Subject ID.
Arm	ARM	Placebo, Creatine	Treatment arm.
Age (yrs)	AGE		Subject age at on-study.
Follow-up Time (days)	FU_TIME		Total follow-up time.
Follow-up Status	FU_STAT	Dead, Alive	Follow-up status.
Time on study (days)	ON_TIME		Total time on study.
Primary Tumor Site	LOC_PRI	Other, Lung, GI	Tumor site on-study.
Related Weight Loss	WT_LOSS	>=4.6 KG, <4.6 KG	Prior weight loss at on-study.
Concurrent Chemo	CON_CT	Yes, No	Current chemotherapy at on-study.
Age Group (years)	AGE_G	>=50, <50	Age group at on-study.
Gender	GENDER	Female, Male	Subject gender.
GBU Prog Index	GBU	BAD, UNSURE, GOOD	Prognostic index at on-study.
Excluded reason	EXCLUDED	Cancellation, Eligible, Ineligible,	Subject eligibility vs non-eligibility.

		Major violation	
Grade 3+ Adverse Event	GR3	No, Yes	Whether or not a subject experienced a grade 3+ adverse event.
Grade 3+ Hematologic Adverse Event	GR3H	No, Yes	Whether or not a subject experienced a grade 3+ hematologic adverse event.
Grade 3+ Non-hematologic Adverse Event	GR3NH	No, Yes	Whether or not a subject experienced a grade 3+ non-hematologic adverse event.
Grade 4+ Adverse Event	GR4	No, Yes	Whether or not a subject experienced a grade 4+ adverse event.
Grade 4+ Hematologic Adverse Event	GR4H	No, Yes	Whether or not a subject experienced a grade 4+ hematologic adverse event.
Grade 4+ Non-hematologic Adverse Event	GR4NH	No, Yes	Whether or not a subject experienced a grade 4+ non-hematologic adverse event.
Grade 5 Adverse Event	GR5	No, Yes	Whether or not a subject experienced a grade 5 adverse event.
One month percent change in weight from baseline	CYC1_WTCHG		Weight change from baseline at month one (percentage).
Greatest percent change in weight from baseline	MAX_WTCHG		Greatest change from baseline over course of study (percentage).