

A221303

Randomized Study of Early Palliative Care Integrated With Standard Oncology Care Versus Standard Oncology Care Alone in Patients With Incurable Lung or Non-Colorectal Gastrointestinal Malignancies

ClinicalTrial.gov Identifier: NCT02349412

Study Background

Trial Description

The study intervention consists of the early integration of palliative care services into standard oncology care in an outpatient setting for patients with advanced lung and non-colorectal gastrointestinal malignancies who are not being treated with curative intent. The palliative care services provided to patients randomized to the intervention will be provided by board-certified physicians and/or advanced practice nurses and will focus on the following areas: (1) developing and maintaining the therapeutic relationship with the patients and family caregivers; (2) assessing and treating patient symptoms; (3) providing support and reinforcement of coping with advanced cancer in patients and family caregivers; (4) assessing and enhancing prognostic awareness and illness understanding in patients and family caregivers; (5) assisting with treatment decision-making; and (6) end-of-life care planning.

Arms:

Arm 1: (Experimental): Patients receive early palliative care and standard oncology care. Patients and family caregivers will be asked to complete quality-of-life questionnaires at weeks 6, 12, and 24. Survival follow-up will be every 4 months from week 24 until death or up to 3 years.

Arm 2: (Control): Patients receive standard oncology care. Patient and family caregiver will be asked to complete self-report questionnaires at weeks 6, 12, and 24. Survival follow-up will be every 4 months from week 24 until death or up to 3 years. Palliative care visit only upon request from attending oncologist(s) or patient/family.

Objectives:

Primary Endpoint:

- To determine the efficacy of early integrated palliative care on patient reported quality of life at 12 weeks using the FACT in patients with newly diagnosed incurable lung or non-colorectal gastrointestinal cancer.

Secondary Endpoints:

- To determine the efficacy of early integrated palliative care on other patient reported outcomes in patients with newly diagnosed incurable lung or non-colorectal gastrointestinal cancer, by assessing the endpoints defined in the protocol.
- To determine the efficacy of early integrated palliative care on family caregiver reported outcomes in those newly diagnosed incurable lung or non-colorectal gastrointestinal cancer, by assessing the endpoints defined in the protocol.
- To assess the impact of early integrated palliative care on the quality of end-of-life care and resource utilization in patients with newly diagnosed incurable lung or non-colorectal gastrointestinal cancer by assessing the endpoints defined in the protocol.
- To determine concordance between patient and family caregiver report of prognosis/curability.

Study Milestones:

Primary Completion Date: July 3, 2017

Publication Information:

Analysis Type: Primary

PubMed ID: 32031887

Citation: J Palliat Med. 2020 Jul;23(7):922-929. doi: 10.1089/jpm.2019.0377. Epub 2020 Feb 7.

Associated Datasets:

NCT02349412-D1-Dataset.csv (nctn_consort),

NCT02349412-D2-Dataset.csv (nctn_table1),

NCT02349412-D3-Dataset.csv (nctn_table2),

NCT02349412-D4-Dataset.csv (nctn_table3),

NCT02349412-D5-Dataset.csv (nctn_table4),

NCT02349412-D6-Dataset.csv (nctn_fig2),

NCT02349412-D7-Dataset.csv (nctn_supp_table1),

NCT02349412-D8-Dataset.csv (nctn_supp_table2),

NCT02349412-D9-Dataset.csv (nctn_supp_table3)

Dataset Information:

Dataset Name: NCT02349412-D2-Dataset.csv (nctn_table1)

Description: Dataset NCT02349412-D2-Dataset.csv (nctn_table1) is one of 9 datasets associated with PubMed ID 32031887. This dataset contains information that will allow you to reproduce Table 1 from the manuscript.

Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).

Blank values indicate data missing, except where otherwise noted.

NCT02349412-D2-Dataset.csv (nctn_table1) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Age (years)	AGE		For de-identification purposes, patients >90 were given the value ">90"
Data Center ID	patref		
Race	RACE1	White, Black or African American, American Indian or Alaska Native, Asian, Not reported: patient refused or not available, Unknown: Patient unsure, Native Hawaiian or Other Pacific Islander	
Gender	SEX	f = "Female", m = "Male"	
Caregiver participation	CGPART	No, Yes	
Tumor type	TUMRTYP	Lung, Hepatic/Biliary/Pancreatic/Unknown primary, Esophageal/GEJ/Gastric	
Arm	ARM	1 = "Early Palliative Care", 2 = "Standard Oncology Care"	
ECOG PS	ECOGPS	0, 1, 2	

LABEL	NAME	ELEMENTS	COMMENTS
Ethnicity	PTETHNCTY	Not Hispanic or Latino, Not Reported, Unknown, Hispanic or Latino	
What is the highest grade you finished in school?	PTHIGHEDU	Bachelor's degree, Associate degree/some college, High school graduate/GED, Advanced degree, 9-11th grade, 8th grade or less, I prefer not to answer, Vocational/technical school	
What is your marital status?	PTMARGSTAT	Domestic partnership, Divorced, Married, Widowed, Never married, Separated, I prefer not to answer, Unknown/Not reported	
Religion	PTRELGN	Catholic, Other, Jewish, Protestant, Not reported, None, Unknown, Muslim	
FACTG Baseline - Raw	fact_bl		
HADS-PT Anxiety Baseline - Raw	hads_pt_anx_bl		
HADS-PT Depression Baseline - Raw	hads_pt_dep_bl		
OS Time (months)	fu_months		
OS Status	dead	0 = "Alive" 1 = "Deceased"	
PC Visits by Week 12	n12		

PC Visits by Week 24	n24		
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