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-D1-Dataset.csv (nctn_consort)

Description: Dataset NCT02349412-D1-Dataset.csv (nctn_consort) is one of 9 datasets associated with PubMed ID 32031887. This dataset contains information that will allow you to reproduce the consort diagram.

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 not applicable or missing, except where otherwise noted.

NCT02349412-D1-Dataset.csv (nctn_consort) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Arm	ARM	1 = “Early Palliative Care”, 2 = "Standard Oncology Care"	
De-identified patient reference	patref		
Did Not Complete Baseline QOL Assessment Reason	bsl_assess_specify	Unknown reason/other, Completed outside of protocol window, Patient deceased	Reason why patient did not complete baseline QOL assessment
Did Not Complete Week 12 QOL Assessment Reason	wk12_assess_specify	Patient deceased, Completed outside of protocol window, Unknown reason/other	Reason why patient did not complete week 12 QOL assessment
Did Not Complete Week 24 QOL Assessment Reason	wk24_assess_specify	Patient deceased, Unknown reason/other, Completed outside of protocol window	Reason why patient did not complete week 24 QOL assessment
Patient withdrew	withdraw	0 = “Did Not Withdraw”, 1 = “Withdrew”	Indicator for whether patient withdrew from study

LABEL	NAME	ELEMENTS	COMMENTS
Completed Baseline QOL Assessment	bsl_assess_complete	0= “Not assessed at Baseline”, 1 = “Assessed at Baseline”	Indicator for whether patient completed baseline QOL assessment. Missing values indicate patient withdrew prior to intervention.
Completed Week 12 QOL Assessment	wk12_assess_complete	0= “Not assessed at Week 12”, 1 = “Assessed at Week 12”	Indicator for whether patient completed week 12 QOL assessment. Missing values indicate patient withdrew prior to intervention.
Completed Week 24 QOL Assessment	wk24_assess_complete	0= “Not assessed at Week 24”, 1 = “Assessed at Week 24”	Indicator for whether patient completed week 24 QOL assessment. Missing values indicate patient withdrew prior to intervention.