

## Alliance for Clinical Trials in Oncology N0574:

# Phase III Randomized Trial of the Role of Whole Brain Radiation Therapy in Addition to Radiosurgery in the Management of Patients with One to Three Cerebral Metastases

ClinicalTrials.gov Identifier: NCT00377156

## Study Background

**Trial Design:** A randomized phase III trial, using a 1:1 randomization, patients go on to

- Arm A: Radiosurgery (SRS)
- Arm B: Radiosurgery (SRS) + Whole Brain Radiation (WBRT)

This study was designed to include 70 patients who were accrued by Z0300, as N0574 is meant to be a continuation of ACOSOG Z0300.

**Objectives:** Primary

To ascertain in patients with one to three brain metastases whether there is less neurocognitive progression at 3 months post-radiosurgery in patients who receive SRS alone (Arm A) compared to patients who receive SRS combined with WBRT (Arm B).

### Secondary

- To ascertain in patients with one to three brain metastases whether there is equal (or greater) time to central nervous system (CNS) failure (brain) in patients who receive SRS alone (Arm A) compared to patients who receive SRS combined with WBRT (Arm B).
- To ascertain in patients with one to three brain metastases whether there is improved QOL in patients who receive SRS alone (Arm A) compared to patients who receive SRS combined with WBRT (Arm B).
- To ascertain in patients with one to three brain metastases whether there is longer duration of functional independence in patients who receive SRS alone (Arm A) compared to patients who receive SRS combined with WBRT (Arm B).
- To ascertain in patients with one to three brain metastases whether there is better long-term neurocognitive status in patients who receive SRS alone (Arm A) compared to patients who receive SRS combined with WBRT (Arm B).
- To tabulate and descriptively compare the post-treatment adverse events associated with the interventions.

- To compare in patient with one to three brain metastases the overall survival in patients who receive SRS alone (Arm A) compared to patients who receive SRS combined with WBRT (Arm B).

**Stratification  
Factors:**

1. Age (years)
  - 18 to 59
  - $\geq 60$
2. Extracranial disease controlled (months)
  - $\leq 3$
  - $> 3$
3. Number of brain metastases
  - 1
  - 2
  - 3

**Study  
History:**

- 07/28/2006 Study was activated. This trial is a continuation of the ACOSOG trial Z0300, which was closed by ACOSOG leadership in 2004.
- 10/24/2008 Amendment 3, updated the objectives of the study to make neurocognitive progression the primary endpoint.
- 12/19/2013 Study permanently closed to accrual.

## **Publication Information**

**Analysis Type:** Primary Endpoint Analysis

**PubMed ID:** 27458945

**Citation:** Brown PD, Jaeckel K, Ballman KV, Farace E, Cerhan JH, Anderson SK, Carrero XW, Barker FG, Deming R, Burri SH, Ménard C, Chung C, Stieber VW, Pollock BE, Galanis E, Buckner JC, Asher, AL. Effect of Radiosurgery Alone vs Radiosurgery With Whole Brain Radiation Therapy on Cognitive Function in Patients With 1 to 3 Brain Metastases: A Randomized Clinical Trial. *JAMA*. 2016;316(4):401-409. doi:10.1001/jama.2016.9839

**Associated Datasets:** NCT0377156-D1 (BASE)  
NCT0377156-D2 (NCOG3MO)  
NCT0377156-D3 (QOLDATA)  
NCT0377156-D4 (LTSURV)  
NCT0377156-D5 (AE3PLUS)

## **Dataset Information**

**Dataset Name:** NCT00377156-D3 (QOLDATA)

**Description:** The NCT00377156-D3 (QOLDATA) dataset is one of 5 datasets associated with PubMed ID 27458945. This dataset includes one record per patient for QOL Scores at 3-month, 6-month, and 9-month evaluations. Baseline values for QOL data are included in NCT00377156-D1 (BASE) dataset.

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)

## **NCT00377156-D3 (QOLDATA) Data Dictionary**

<b>Variable Name</b>	<b>Variable Description</b>	<b>Codes</b>	<b>Notes</b>
STUDY_ID	Study Identifier	N0574	
SUBJECT	Subject	Character values	De-identified patient ID
ARM	Randomized Treatment Arm	A = SRS B = SRS + WBRT	SRS = Radiosurgery WBRT = Whole Brain Radiotherapy
EVALUABL	Evaluable for primary analysis	Y = Yes N = No	111 were included in the primary end point analysis as defined in the study protocol.
timepoint	Time point	1 = 3-Month 2 = 6-Month 3 = 9-Month	
<p><b>QOL FACT-BR Scores and Subscores</b></p> <p>If more than 50% of items in each subscore are missing, then the subscore value is not computed and it is set to missing. This applies to each subscore: pwb, sfwb, ewb, fwb, factg, br, factbr.</p> <p>For all scores, higher scores indicate better quality of life.</p>			
pwb	Physical Well-Being Subscore	0-28	Raw scores (generated by scoring algorithm) missing =data is unavailable
sfwb	Social/Family Well-Being Subscore	0-28	
ewb	Emotional Subscore	0-24	
fwb	Functional Subscore	0-28	

<b>Variable Name</b>	<b>Variable Description</b>	<b>Codes</b>	<b>Notes</b>
factg	FACT-Br General Score	0-108	
br	Additional Concerns	0-92	
factbr	FACT-Br Total Score	0-200	
<b>Other QOL measures</b>			
barthel	Barthel ADL index (Functional Independence)	0 to 100 in 5-point increments Missing = patient not evaluated / data unavailable.	