Safety and Tolerability of Low-Dose Temozolomide During Whole Brain Radiation in Patients With Cerebral Metastases From Non-Small-Cell Lung Cancer (Study P04071)(TERMINATED)

This study has been terminated.

(Patient target could not be reached within the planned timeframe.)

Sponsor:
Merck Sharp & Dohme Corp.

Collaborator:
AESCA Pharma GmbH

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00266812

First received: December 16, 2005
Last updated: April 29, 2015
Last verified: April 2015
History of Changes

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Purpose

This is a phase II, randomized, multicenter, open-label study designed to assess the safety and tolerability of concomitant chemotherapy with low-dose temozolomide during whole brain radiation and later on at 14 days on/14 days off schedule in patients with cerebral metastases from non-small cell lung cancer (NSCLC). The response to temozolomide will be evaluated by clinical follow up and Magnetic Resonance Imaging (MRI) performed every 2 months. Progression-free survival at 6 months, duration of overall survival, and quality of life will also be evaluated.

Condition	Intervention	Phase
Carcinoma, Non-Small-Cell Lung	Drug: Temozolomide and radiotherapy Procedure: Whole brain radiotherapy	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Randomized Phase II Study: Temozolomide (TMZ) Concomitant to Radiotherapy Followed by Sequential TMZ in Advanced Non-Small Cell Lung Cancer (NSCLC) Patients With Central Nervous System (CNS) Metastasis Versus Radiotherapy Alone

Resource links provided by NLM:

Genetics Home Reference related topics: lung cancer

MedlinePlus related topics: Lung Cancer

Drug Information available for: Temozolomide

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Number of Participants With Progression-free Survival (6 Month) [Time Frame: 6 months] [Designated as safety issue: No]

  The occurrence of progression will be compared between the study groups by Kaplan-Meier curves. Responsiveness to temozolomide will be evaluated by brain Magnetic Resonance Imanging (MRI)/Computed Tomography (CT), thorax CT, and Quality of Life (QoL) assessments. Progression-free is defined as <25% increase in tumor size on CT or MRI.

Enrollment:	35
Study Start Date:	March 2005
Study Completion Date:	January 2008
Primary Completion Date:	January 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Chemotherapy with temozolomide and radiotherapy	Drug: Temozolomide and radiotherapy Oral temozolomide 75mg/m2/day for 14 days, during radiation treatment, and later on temozolomide 100 mg/m2/day at 14 days on/14 days off, until unacceptable toxicity or evidence of disease progression for up to 6 cycles from initial treatment. Radiotherapy (as in Intervention 2). Other Name: Temodal, TMZ, SCH 052365
Active Comparator: Radiotherapy alone	Procedure: Whole brain radiotherapy 2 regimens are allowed: a) 20 fractions of 2 Gray each, administered on days 1 to 5, 8 to 12, 15 to 19, and 22 to 26; b) 10 fractions of 3 Gray each, administered on days 1 to 5 and 8 to 12.

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Prior histologic confirmation of non-small cell lung cancer (NSCLC).
- Optional: NSCLC histologic confirmation of metastasis of NSCLC.
- Presence of unidimensionally measurable disease in the brain.
- No previous or current malignancies at other sites with the exception of adequately treated in situ carcinoma of the cervix or basal and squamous carcinoma of the skin.
- Age: >18 years.
- Subjects must not have systemic disease that in the opinion of the investigator is in immediate need of chemotherapy
- Karnofsky Performance status >=70%.
- Absolute neutrophil count (ANC) >1,500/mm^3, platelets >100,000/mm^3, hemoglobin >8 g/dL.
- Serum creatinine and bilirubin <1.5 times upper normal limit of testing laboratory.
- Serum glutamic oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT) <3 times upper limit of testing laboratory.
- Palliative radiation therapy to thorax and bone or other organs (except brain) is acceptable.
- Prior neurosurgery >2 weeks from initiating treatment with temozolomide.
- Cortisone medication stable or decreasing within 2 weeks prior to initiating treatment with temozolomide.
- Patient is not pregnant or nursing and is advised and willing to use an effective method of contraception.
- Written informed consent.

Exclusion Criteria:

- Chemotherapy or biologic therapy within four weeks prior to initiating therapy with temozolomide.
- Prior radiation therapy for brain <4 weeks from initiating therapy with temozolomide.
- Surgery within two weeks prior to temozolomide administration.
- Recursive Partitioning Analysis (RPA) class III
- Patients with a single brain metastasis amenable to radiosurgery of resection
- Known Human Immunodeficiency Virus (HIV) disease.
- Acute infection requiring intravenous antibiotics.
- Any reason making compliance to the protocol improbable.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

No Contacts or Locations Provided

More Information

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00266812 History of Changes
Other Study ID Numbers:	**P04071**
Study First Received:	December 16, 2005
Results First Received:	July 29, 2009
Last Updated:	April 29, 2015
Health Authority:	Austria: Federal Ministry for Health and Women

Keywords provided by Merck Sharp & Dohme Corp.:
temozolomide
radiotherapy

Additional relevant MeSH terms:

Carcinoma, Non-Small-Cell Lung	Lung Diseases
Carcinoma, Bronchogenic	Respiratory Tract Diseases
Bronchial Neoplasms	Temozolomide
Lung Neoplasms	Dacarbazine
Respiratory Tract Neoplasms	Antineoplastic Agents, Alkylating
Thoracic Neoplasms	Alkylating Agents
Neoplasms by Site	Molecular Mechanisms of Pharmacological Action
Neoplasms	Antineoplastic Agents

ClinicalTrials.gov processed this record on July 26, 2016

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Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Carcinoma, Non-Small-Cell Lung
Interventions:	Drug: Temozolomide and radiotherapy Procedure: Whole brain radiotherapy

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Chemotherapy With Temozolomide and Radiotherapy	Oral temozolomide 75mg/m2/day for 14 days, during radiation treatment, and later on temozolomide 100mg/m2/day at 14 days on/14 days off, until unacceptable toxicity or evidence of disease progression for up to 6 cycles from initial treatment. Radiotherapy (as in Intervention 2).
Radiotherapy Alone	2 regimens are allowed: a) 20 fractions of 2 Gray each, on days 1 to 5, 8 to 12, 15 to 19, and 22 to 26; b) 10 fractions of 3 Gray each, administered on days 1 to 5 and 8 to 12.

Participant Flow: Overall Study

	Chemotherapy With Temozolomide and Radiotherapy	Radiotherapy Alone
STARTED	**22**	**13**
COMPLETED	**1**	**2**
NOT COMPLETED	**21**	**11**
Disease Progression	**9**	**3**
Death	**5**	**4**
Adverse Event	**3**	**1**
Protocol Violation	**0**	**1**
Withdrawal by Subject	**0**	**2**
Discontinued before starting study drug	**4**	**0**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Chemotherapy With Temozolomide and Radiotherapy	Oral temozolomide 75mg/m2/day for 14 days, during radiation treatment, and later on temozolomide 100mg/m2/day at 14 days on/14 days off, until unacceptable toxicity or evidence of disease progression for up to 6 cycles from initial treatment. Radiotherapy (as in Intervention 2).
Radiotherapy Alone	2 regimens are allowed: a) 20 fractions of 2 Gray each, on days 1 to 5, 8 to 12, 15 to 19, and 22 to 26; b) 10 fractions of 3 Gray each, administered on days 1 to 5 and 8 to 12.
Total	Total of all reporting groups

Baseline Measures

	Chemotherapy With Temozolomide and Radiotherapy	Radiotherapy Alone	Total

Number of Participants [units: participants]	**22**	**13**	**35**
Age [units: years] Mean (Standard Deviation)	**65.12 (12.72)**	**63.02 (8.76)**	**64.3 (11.3)**
Gender [units: participants]			
Female	**9**	**5**	**14**
Male	**13**	**8**	**21**

Outcome Measures

1. Primary: Number of Participants With Progression-free Survival (6 Month) [Time Frame: 6 months]

Show Outcome Measure 1

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. **Restriction Description:** No text entered.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck, Sharp & Dohme Corp
e-mail: ClinicalTrialsDisclosure@merck.com

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