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Temozolomide as a Prophylaxis Against Brain Recurrence in Participants With Metastatic Breast Cancer (P05225 AM2) (STOP)

This study has been terminated.

(Terminated due to poor accrual)

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00638963

First received: January 10, 2008
Last updated: January 19, 2015
Last verified: January 2015
History of Changes

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Purpose

The purpose of this study is to determine whether temozolomide can be used as a prophylaxis against brain recurrence in participants with metastatic breast cancer.

Condition	Intervention	Phase
Breast Neoplasm Brain Neoplasm Second Neoplasm	Drug: temozolomide	Phase 2

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

Official Title: Temozolomide in Metastatic Breast Cancer Patients at High Risk of Brain Recurrence: Impact on the Incidence of Brain Metastases (STOP)

Resource links provided by NLM:

Genetics Home Reference related topics: breast cancer

MedlinePlus related topics: Breast Cancer Cancer

Drug Information available for: Temozolomide

U.S. FDA Resources

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

Primary Outcome Measures:

- Percent of Participants With Recurrence of Brain Metastases [Time Frame: 1 Year] [Designated as safety issue: No]

  The analysis could not be performed due to low enrollment.

Secondary Outcome Measures:

- Number of Days With Progression-free Survival (PFS) [Time Frame: 24, 38, and 52 weeks] [Designated as safety issue: No]

  PFS was defined as the time interval from randomization to objective tumor progression or death from any cause. The analysis could not be performed due to low enrollment.

- Number of Days With Disease-free Survival (DFS) [Time Frame: 24, 38, and 52 weeks] [Designated as safety issue: No]

  DFS was defined as the time interval from randomization to any relapse (loco-regional, contra-lateral, and/or distant). The analysis could not be performed due to low enrollment.

- Number of Days With Distant Disease-free Survival (DDFS) [Time Frame: 24, 38, and 52 weeks] [Designated as safety issue: No]

  DDFS was defined as the time interval from randomization to only distant metastases (for example, bone, visceral organ, brain). The analysis could not be performed due to low enrollment.

- Number of Days With Brain Recurrence-free Survival (BRFS) [Time Frame: 24,38, and 52 weeks] [Designated as safety issue: No]

  BRFS was defined as the time interval from randomization to the appearance of brain metastases. The analysis could not be performed due to low enrollment.

- Number of Days on Temozolomide Treatment [Time Frame: Baseline to 24 Weeks] [Designated as safety issue: No]

  This outcome measure was only applicable to the temozolomide arm; the observation arm was therefore not analyzed.

- Total Dose of Temozolomide Taken [Time Frame: Baseline to 24 Weeks] [Designated as safety issue: No]

  This outcome measure was only applicable to the temozolomide arm; the observation arm was therefore not analyzed.

- Number of Participants Who Had at Least One Dose Reduction During Treatment [Time Frame: Baseline to 24 Weeks] [Designated as safety issue: No]

  This outcome measure was only applicable to the temozolomide arm; the observation arm was therefore not analyzed.

- Number of Participants Who Had at Least One Treatment Omission During Treatment [Time Frame: Baseline to 24 Weeks] [Designated as safety issue: No]

  This outcome measure was only applicable to the temozolomide arm; the observation arm was therefore not analyzed.

- Number of Participants Who Completed the Third Cycle of Treatment [Time Frame: Baseline to 24 Weeks] [Designated as safety issue: No]

  This outcome measure was only applicable to the temozolomide arm; the observation arm was therefore not analyzed.

Enrollment:	6
Study Start Date:	October 2008
Study Completion Date:	June 2010
Primary Completion Date:	June 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Temozolomide	Drug: temozolomide Capsules to equal 75 mg/m^2, orally, daily for 6 weeks, in 3 eight-week cycles
No Intervention: Observational	

Detailed Description:

Breast cancer is the second most common cause of brain metastases. Overall survival after the development of brain metastases tends to be poor (6-8 months). Over-expression of Human Epidermal Growth Factor Receptor 2 (HER-2/neu), negative estrogen receptor, and young age at diagnosis seem to be indicators of high risk for brain metastases. Temozolomide may be a good candidate for prophylactic chemotherapy because of its ability to cross the blood-brain-barrier, achieving high concentrations in the central nervous system (CNS).

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Diagnosis of metastatic breast cancer.
- Participants must have completed first line of metastatic chemotherapy and have achieved complete or partial response or disease stability for at least 6 months from the first confirmation of disease stabilization.
- No clinical sign of brain progression.
- At least one of the following 3 conditions: HER2 +++, Young age (< 50 years), and/or estrogen receptor (ER)-/progesterone receptor (PgR)-
- Eastern Cooperative Oncology Group (ECOG) performance status ≤2.
- Life expectancy ≥3 months.
- Neutrophils ≥1.5 x 10^9/L, platelets ≥100 x 10^9/L, hemoglobin ≥9 g/dL, lymphocytes ≥1 x 10^9/L.
- Bilirubin level either normal or <1.5 x ULN (upper limit of normal).
- AST (aspartate aminotransferase) and ALT (alanine aminotransferase) ≤2.5 x ULN (≤5 x ULN if liver metastases are present).
- Serum creatine <1.5 x ULN.
- Effective contraception if the risk of conception exists.

Exclusion Criteria:

- Concurrent chronic systemic immune therapy not indicated in the study protocol.
- Any investigational agent(s) within 4 weeks prior to entry.
- Participants that have completed 2nd, 3rd, or 4th line metastatic chemotherapy or participant in active chemotherapy treatment.
- Clinically relevant coronary artery disease or a history of a myocardial infarction within the last 12 months.
- Acute or sub acute intestinal occlusion or history of inflammatory bowel disease.
- Known Grade 3 or Grade 4 allergic reaction to any of the components of the treatment.
- Known drug abuse/alcohol abuse.
- Legal incapacity or limited legal capacity.
- Medical or psychological condition which in the opinion of the investigator would not permit the participant to complete the study or sign meaningful informed consent.
- Women who are pregnant or breastfeeding.
- Any concurrent malignancy other than non-melanoma skin cancer, or carcinoma in situ of the cervix (participants with a previous malignancy but without evidence of disease for ≥5 years will be allowed to enter the trial).

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

No publications provided

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00638963 History of Changes
Other Study ID Numbers: P05225 2007-005491-14

Study First Received: January 10, 2008
Results First Received: June 23, 2011
Last Updated: January 19, 2015
Health Authority: Italy: Ministry of Health

Additional relevant MeSH terms:

- Brain Neoplasms
- Breast Neoplasms
- Neoplasms
- Neoplasms, Second Primary
- Brain Diseases
- Breast Diseases
- Central Nervous System Diseases
- Central Nervous System Neoplasms
- Neoplasms by Site
- Nervous System Diseases
- Nervous System Neoplasms
- Skin Diseases
- Temozolomide
- Alkylating Agents
- Antineoplastic Agents
- Antineoplastic Agents, Alkylating
- Molecular Mechanisms of Pharmacological Action
- Pharmacologic Actions
- Therapeutic Uses

ClinicalTrials.gov processed this record on April 10, 2016

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Results First Received: June 23, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Prevention
Conditions:	Breast Neoplasm Brain Neoplasm Second Neoplasm
Intervention:	Drug: temozolomide

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
Temozolomide	Capsules to equal 75 mg/m^2, orally, daily for 6 weeks, in 3 eight-week cycles
Observational	No temozolomide treatment

Participant Flow: Overall Study

	Temozolomide	Observational
STARTED	3 [1]	3 [1]
COMPLETED	2 [2]	3 [2]
NOT COMPLETED	1	0
Withdrawal by Subject	1	0

[1] Received randomized treatment assignment
[2] including follow-up at Week 38 & Week 52

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
Temozolomide	Capsules to equal 75 mg/m^2, orally, daily for 6 weeks, in 3 eight-week cycles
Observational	No temozolomide treatment
Total	Total of all reporting groups

Baseline Measures

	Temozolomide	Observational	Total
Number of Participants [units: participants]	3	3	6
Age [units: participants]			
<=18 years	0	0	0
Between 18 and 65 years	3	3	6
>=65 years	0	0	0
Gender [units: participants]			

Female	**3**	**3**	**6**
Male	**0**	**0**	**0**
Region of Enrollment [units: participants]			
Italy	**3**	**3**	**6**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percent of Participants With Recurrence of Brain Metastases [Time Frame: 1 Year]

Measure Type	Primary
Measure Title	Percent of Participants With Recurrence of Brain Metastases
Measure Description	The analysis could not be performed due to low enrollment.
Time Frame	1 Year
Safety Issue	No

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
Temozolomide	Capsules to equal 75 mg/m^2, orally, daily for 6 weeks, in 3 eight-week cycles
Observational	No temozolomide treatment

Measured Values

	Temozolomide	**Observational**
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent of Participants With Recurrence of Brain Metastases		

No statistical analysis provided for Percent of Participants With Recurrence of Brain Metastases

2. Secondary: Number of Days With Progression-free Survival (PFS) [Time Frame: 24, 38, and 52 weeks]

Measure Type	Secondary
Measure Title	Number of Days With Progression-free Survival (PFS)
Measure Description	PFS was defined as the time interval from randomization to objective tumor progression or death from any cause.

	The analysis could not be performed due to low enrollment.
Time Frame	24, 38, and 52 weeks
Safety Issue	No

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
Temozolomide	Capsules to equal 75 mg/m^2, orally, daily for 6 weeks, in 3 eight-week cycles
Observational	No temozolomide treatment

Measured Values

	Temozolomide	**Observational**
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Days With Progression-free Survival (PFS)		

No statistical analysis provided for Number of Days With Progression-free Survival (PFS)

3. Secondary: Number of Days With Disease-free Survival (DFS) [Time Frame: 24, 38, and 52 weeks]

Measure Type	Secondary
Measure Title	Number of Days With Disease-free Survival (DFS)
Measure Description	DFS was defined as the time interval from randomization to any relapse (loco-regional, contra-lateral, and/or distant). The analysis could not be performed due to low enrollment.
Time Frame	24, 38, and 52 weeks
Safety Issue	No

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
Temozolomide	Capsules to equal 75 mg/m^2, orally, daily for 6 weeks, in 3 eight-week cycles
Observational	No temozolomide treatment

Measured Values

	Temozolomide	Observational
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Days With Disease-free Survival (DFS)		

No statistical analysis provided for Number of Days With Disease-free Survival (DFS)

4. Secondary: Number of Days With Distant Disease-free Survival (DDFS) [Time Frame: 24, 38, and 52 weeks]

Measure Type	Secondary
Measure Title	Number of Days With Distant Disease-free Survival (DDFS)
Measure Description	DDFS was defined as the time interval from randomization to only distant metastases (for example, bone, visceral organ, brain). The analysis could not be performed due to low enrollment.
Time Frame	24, 38, and 52 weeks
Safety Issue	No

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
Temozolomide	Capsules to equal 75 mg/m^2, orally, daily for 6 weeks, in 3 eight-week cycles
Observational	No temozolomide treatment

Measured Values

	Temozolomide	Observational
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Days With Distant Disease-free Survival (DDFS)		

No statistical analysis provided for Number of Days With Distant Disease-free Survival (DDFS)

5. Secondary: Number of Days With Brain Recurrence-free Survival (BRFS) [Time Frame: 24,38, and 52 weeks]

Measure Type	Secondary
Measure Title	Number of Days With Brain Recurrence-free Survival (BRFS)
Measure Description	BRFS was defined as the time interval from randomization to the appearance of brain metastases. The analysis could not be performed due to low enrollment.
Time Frame	24,38, and 52 weeks
Safety Issue	No

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
Temozolomide	Capsules to equal 75 mg/m^2, orally, daily for 6 weeks, in 3 eight-week cycles
Observational	No temozolomide treatment

Measured Values

	Temozolomide	**Observational**
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Days With Brain Recurrence-free Survival (BRFS)		

No statistical analysis provided for Number of Days With Brain Recurrence-free Survival (BRFS)

6. Secondary: Number of Days on Temozolomide Treatment [Time Frame: Baseline to 24 Weeks]

Measure Type	Secondary
Measure Title	Number of Days on Temozolomide Treatment
Measure Description	This outcome measure was only applicable to the temozolomide arm; the observation arm was therefore not analyzed.
Time Frame	Baseline to 24 Weeks
Safety Issue	No

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

Temozolomide	Capsules to equal 75 mg/m^2, orally, daily for 6 weeks, in 3 eight-week cycles

Measured Values

	Temozolomide
Number of Participants Analyzed [units: participants]	**3**
Number of Days on Temozolomide Treatment [units: Days] Mean (Standard Deviation)	**75 (65.82)**

No statistical analysis provided for Number of Days on Temozolomide Treatment

7. Secondary: Total Dose of Temozolomide Taken [Time Frame: Baseline to 24 Weeks]

Measure Type	Secondary
Measure Title	Total Dose of Temozolomide Taken
Measure Description	This outcome measure was only applicable to the temozolomide arm; the observation arm was therefore not analyzed.
Time Frame	Baseline to 24 Weeks
Safety Issue	No

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
Temozolomide	Capsules to equal 75 mg/m^2, orally, daily for 6 weeks, in 3 eight-week cycles

Measured Values

	Temozolomide
Number of Participants Analyzed [units: participants]	**3**
Total Dose of Temozolomide Taken [units: Milligrams] Mean (Standard Deviation)	**9791.9 (8732.0)**

No statistical analysis provided for Total Dose of Temozolomide Taken

8. Secondary: Number of Participants Who Had at Least One Dose Reduction During Treatment [Time Frame: Baseline to 24 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants Who Had at Least One Dose Reduction During Treatment
Measure Description	This outcome measure was only applicable to the temozolomide arm; the observation arm was therefore not analyzed.
Time Frame	Baseline to 24 Weeks
Safety Issue	No

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
Temozolomide	Capsules to equal 75 mg/m^2, orally, daily for 6 weeks, in 3 eight-week cycles

Measured Values

	Temozolomide
Number of Participants Analyzed [units: participants]	**3**
Number of Participants Who Had at Least One Dose Reduction During Treatment [units: Participants]	**3**

No statistical analysis provided for Number of Participants Who Had at Least One Dose Reduction During Treatment

9. Secondary: Number of Participants Who Had at Least One Treatment Omission During Treatment [Time Frame: Baseline to 24 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants Who Had at Least One Treatment Omission During Treatment
Measure Description	This outcome measure was only applicable to the temozolomide arm; the observation arm was therefore not analyzed.
Time Frame	Baseline to 24 Weeks
Safety Issue	No

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
Temozolomide	Capsules to equal 75 mg/m^2, orally, daily for 6 weeks, in 3 eight-week cycles

Measured Values

	Temozolomide
Number of Participants Analyzed [units: participants]	**3**
Number of Participants Who Had at Least One Treatment Omission During Treatment [units: Participants]	**2**

No statistical analysis provided for Number of Participants Who Had at Least One Treatment Omission During Treatment

10. Secondary: Number of Participants Who Completed the Third Cycle of Treatment [Time Frame: Baseline to 24 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants Who Completed the Third Cycle of Treatment
Measure Description	This outcome measure was only applicable to the temozolomide arm; the observation arm was therefore not analyzed.
Time Frame	Baseline to 24 Weeks
Safety Issue	No

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
Temozolomide	Capsules to equal 75 mg/m^2, orally, daily for 6 weeks, in 3 eight-week cycles

Measured Values

	Temozolomide
Number of Participants Analyzed [units: participants]	**3**
Number of Participants Who Completed the Third Cycle of Treatment [units: Participants]	**2**

No statistical analysis provided for Number of Participants Who Completed the Third Cycle of Treatment

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Temozolomide	Capsules to equal 75 mg/m^2, orally, daily for 6 weeks, in 3 eight-week cycles
Observational	No temozolomide treatment

Serious Adverse Events

	Temozolomide	Observational
Total, serious adverse events		
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Temozolomide	Capsules to equal 75 mg/m^2, orally, daily for 6 weeks, in 3 eight-week cycles
Observational	No temozolomide treatment

Other Adverse Events

	Temozolomide	Observational
Total, other (not including serious) adverse events		
# participants affected / at risk	**2/3 (66.67%)**	**2/3 (66.67%)**

Gastrointestinal disorders		
Diarrhoea † 1		
# participants affected / at risk	**1/3 (33.33%)**	**0/3 (0.00%)**
# events	**1**	**0**
Nausea † 1		
# participants affected / at risk	**2/3 (66.67%)**	**0/3 (0.00%)**
# events	**6**	**0**
Vomiting † 1		
# participants affected / at risk	**1/3 (33.33%)**	**0/3 (0.00%)**
# events	**3**	**0**
General disorders		
Asthenia † 1		
# participants affected / at risk	**1/3 (33.33%)**	**0/3 (0.00%)**
# events	**1**	**0**
Chest pain † 1		
# participants affected / at risk	**0/3 (0.00%)**	**1/3 (33.33%)**
# events	**0**	**1**
Influenza like illness † 1		
# participants affected / at risk	**1/3 (33.33%)**	**0/3 (0.00%)**
# events	**1**	**0**
Pyrexia † 1		
# participants affected / at risk	**1/3 (33.33%)**	**0/3 (0.00%)**
# events	**1**	**0**
Musculoskeletal and connective tissue disorders		
Myalgia † 1		
# participants affected / at risk	**1/3 (33.33%)**	**0/3 (0.00%)**
# events	**1**	**0**
Psychiatric disorders		
Insomnia † 1		
# participants affected / at risk	**1/3 (33.33%)**	**0/3 (0.00%)**
# events	**1**	**0**
Reproductive system and breast disorders		
Vulvovaginal dryness † 1		
# participants affected / at risk	**0/3 (0.00%)**	**1/3 (33.33%)**
# events	**0**	**1**
Skin and subcutaneous tissue disorders		
Erythema † 1		
# participants affected / at risk	**1/3 (33.33%)**	**0/3 (0.00%)**
# events	**1**	**0**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 13.1

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
The primary outcome measure and the survival analyses could not be analyzed due to the low enrollment.

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:** The principal investigator (PI) agrees not to publish or publicly present any interim results of the Study without prior written consent of the sponsor. The PI further agrees to provide 45 days written notice to the sponsor prior to submission for publication or presentation to permit the sponsor to review copies of abstracts or manuscripts for publication in accordance with provisions of laws related to protection of sensitive personal data and patentability of inventions.

Results Point of Contact:

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

No publications provided

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00638963 History of Changes
Other Study ID Numbers:	P05225 2007-005491-14 (EudraCT Number)
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