Study of Asenapine in Elderly Subjects With Psychosis (A7501021)(P05717)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00281320

First received: January 23, 2006
Last updated: February 20, 2015
Last verified: February 2015
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

This study evaluates the safety and tolerability of Asenapine in elderly patients with psychosis.

Condition	Intervention	Phase
Psychosis	Drug: Asenapine	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Randomized, Parallel Group, Multiple Dose, 6-Week Study to Evaluate Safety, Tolerability, and Pharmacokinetics of Asenapine in Elderly Subjects With Psychosis.

Resource links provided by NLM:

MedlinePlus related topics: Mental Disorders Psychotic Disorders

Drug Information available for: Asenapine

U.S. FDA Resources

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

Primary Outcome Measures:

- Number of Participants Who Experienced an Adverse Event [Time Frame: Up to Day 42 (treatment period)] [Designated as safety issue: Yes]
  Participants who experienced treatment-emergent adverse events, defined as newly reported events after baseline or events reported to have

worsened in severity since baseline (from the date of informed consent to the last dose day + 7 days for non-serious adverse events and 30 days for serious adverse events).

- Number of Participants Who Discontinued Because of an Adverse Event [Time Frame: up to 30 days after study medication stop date] [Designated as safety issue: Yes]

  Discontinuations due to treatment-emergent adverse events starting on or after Day1 and up to 7 days after study medication stop date (30 days for serious adverse events).

- Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, Tmax [Time Frame: Day 4 or 8] [Designated as safety issue: No]

  Tmax defined as time to peak concentration.

- Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis,Cmax [Time Frame: Day 4 or 8] [Designated as safety issue: No]

  Cmax defined as peak concentration.

- Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis , Dn-Cmax [Time Frame: Day 4 or 8] [Designated as safety issue: No]

  dn-Cmax is defined as dose normalized peak concentration.

- Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, Cmin [Time Frame: Day 4 or 8] [Designated as safety issue: No]

  Cmin defined as pre-dose concentration.

- Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, AUC 0-12 [Time Frame: Day 4 or 8] [Designated as safety issue: No]

  AUC 0-12 defined as area-under-the-curve from zero to time point 12 hours.

- Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, Dn-AUC 0-12 [Time Frame: Day 4 or 8] [Designated as safety issue: No]

  dn-AUC 0-12 defined as dose-normalized area-under-the-curve from zero to time point 12 hours.

Enrollment:	122
Study Start Date:	February 2006
Study Completion Date:	December 2008
Primary Completion Date:	December 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Asenapine 2-10 mg BID Dose titration from 2 mg to 5 mg to 10 mg twice daily (BID)	Drug: Asenapine Asenapine 2 mg twice daily (BID) on Days 1 and 2, 5 mg BID on Days 3 and 4, followed by 10 mg BID on Day 5 through the end of the trial (Week 6); or Asenapine 5 mg BID on Days 1 to 4 followed by 10 mg BID on Day 5 through the end of the trial (Week 6). Other Name: Saphris
Experimental: Asenapine 5-10mg BID Dose titration from 5 mg to 10 mg BID	Drug: Asenapine Asenapine 2 mg twice daily (BID) on Days 1 and 2, 5 mg BID on Days 3 and 4, followed by 10 mg BID on Day 5 through the end of the trial (Week 6); or Asenapine 5 mg BID on Days 1 to 4 followed by 10 mg BID on Day 5 through the end of the trial (Week 6). Other Name: Saphris

Eligibility

Ages Eligible for Study: 65 Years and older

Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Elderly subjects with psychosis

Exclusion Criteria:

- Have an uncontrolled, unstable clinically significant

medical condition.

- Have an established diagnosis of dementia

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

Publications:

Dubovsky SL, Frobose C, Phiri P, de Greef R, Panagides J. Short-term safety and pharmacokinetic profile of asenapine in older patients with psychosis. Int J Geriatr Psychiatry. 2012 May;27(5):472-82. doi: 10.1002/gps.2737. Epub 2011 Jul 13.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00281320 History of Changes
Other Study ID Numbers: P05717 A7501021
Study First Received: January 23, 2006
Results First Received: August 12, 2010
Last Updated: February 20, 2015
Health Authority: United States: Food and Drug Administration

Additional relevant MeSH terms:

Mental Disorders	Central Nervous System Depressants
Psychotic Disorders	Pharmacologic Actions
Schizophrenia and Disorders with Psychotic Features	Physiological Effects of Drugs
Asenapine	Psychotropic Drugs
Antipsychotic Agents	Therapeutic Uses
Central Nervous System Agents	Tranquilizing Agents

ClinicalTrials.gov processed this record on May 08, 2016

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Results First Received: August 12, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Psychosis
Intervention:	Drug: Asenapine

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

Asenapine 2-10 mg Twice Daily (BID)	Asenapine 2 mg twice daily (BID) on Days 1 and 2, 5 mg BID on Days 3 and 4, followed by 10 mg BID on Day 5 through the end of the trial (Week 6)
Asenapine 5-10 mg BID	Asenapine 5 mg BID on Days 1 to 4 followed by 10 mg BID on Day 5 through the end of the trial (Week 6)

Participant Flow: Overall Study

	Asenapine 2-10 mg Twice Daily (BID)	Asenapine 5-10 mg BID
STARTED	**61**	**61**
COMPLETED	**36**	**40**
NOT COMPLETED	**25**	**21**
Adverse Event	**12**	**9**
Lack of Efficacy	**4**	**3**
Withdrawal by Subject	**5**	**6**
Lost to Follow-up	**1**	**2**
Not specified	**3**	**1**

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
Asenapine 2-10 mg BID	Asenapine 2 mg twice daily (BID) on Days 1 and 2, 5 mg BID on Days 3 and 4, followed by 10 mg BID on Day 5 through the end of the trial (Week 6)
Asenapine 5-10 mg BID	Asenapine 5 mg twice daily (BID) on Days 1 to 4 followed by 10 mg BID on Day 5 through the end of the trial (Week 6)
Total	Total of all reporting groups

Baseline Measures

	Asenapine 2-10 mg BID	Asenapine 5-10 mg BID	Total
Number of Participants [units: participants]	**61**	**61**	**122**
Age [units: years] Mean (Standard Deviation)	**70.5 (4.6)**	**72.0 (5.8)**	**71.2 (5.2)**
Gender [units: participants]			
Female	**41**	**47**	**88**

Male	**20**	**14**	**34**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants Who Experienced an Adverse Event [Time Frame: Up to Day 42 (treatment period)]

Measure Type	Primary
Measure Title	Number of Participants Who Experienced an Adverse Event
Measure Description	Participants who experienced treatment-emergent adverse events, defined as newly reported events after baseline or events reported to have worsened in severity since baseline (from the date of informed consent to the last dose day + 7 days for non-serious adverse events and 30 days for serious adverse events).
Time Frame	Up to Day 42 (treatment period)
Safety Issue	Yes

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.
Per protocol

Reporting Groups

	Description
Asenapine 2-10 mg Twice Daily (BID)	Asenapine 2 mg twice daily (BID) on Days 1 and 2, 5 mg BID on Days 3 and 4, followed by 10 mg BID on Days 5 through the end of the trial (Week 6)
Asenapine 5-10 mg BID	Asenapine 5 mg BID on Days 1 to 4 followed by 10 mg BID on Days 5 through the end of the trial (Week 6)

Measured Values

	Asenapine 2-10 mg Twice Daily (BID)	**Asenapine 5-10 mg BID**
Number of Participants Analyzed [units: participants]	**61**	**61**
Number of Participants Who Experienced an Adverse Event [units: Participants]	**44**	**44**

No statistical analysis provided for Number of Participants Who Experienced an Adverse Event

2. Primary: Number of Participants Who Discontinued Because of an Adverse Event [Time Frame: up to 30 days after study medication stop date]

Measure Type	Primary
Measure Title	Number of Participants Who Discontinued Because of an Adverse Event
Measure Description	Discontinuations due to treatment-emergent adverse events starting on or after Day1 and up to 7 days after study medication stop date (30 days for serious adverse events).

Time Frame	up to 30 days after study medication stop date
Safety Issue	Yes

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.
Per protocol

Reporting Groups

	Description
Asenapine 2-10 mg Twice Daily (BID)	Asenapine 2 mg twice daily (BID) on Days 1 and 2, 5 mg BID on Days 3 and 4, followed by 10 mg BID on Days 5 through the end of the trial (Week 6)
Asenapine 5-10 mg BID	Asenapine 5 mg BID on Days 1 to 4 followed by 10 mg BID on Days 5 through the end of the trial (Week 6)

Measured Values

	Asenapine 2-10 mg Twice Daily (BID)	**Asenapine 5-10 mg BID**
Number of Participants Analyzed [units: participants]	**61**	**61**
Number of Participants Who Discontinued Because of an Adverse Event [units: participants]	**12**	**9**

No statistical analysis provided for Number of Participants Who Discontinued Because of an Adverse Event

3. Primary: Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, Tmax [Time Frame: Day 4 or 8]

Measure Type	Primary
Measure Title	Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, Tmax
Measure Description	Tmax defined as time to peak concentration.
Time Frame	Day 4 or 8
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.
All-Subjects-Pharmacokinetically-Evaluable Group defined as all subjects for which at least one pharmacokinetic parameter could be calculated and who did not have any protocol violations interfering with pharmacokinetics.

Reporting Groups

	Description
Asenapine 5mg BID Day 4	Pharmacokinetic parameter of asepanine for Day 4.
Asenapine 10mg BID Day 8	Pharmacokinetic parameter of asepanine for Day

	8.

Measured Values

	Asenapine 5mg BID Day 4	Asenapine 10mg BID Day 8
Number of Participants Analyzed [units: participants]	**87**	**60**
Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, Tmax [units: hours] Median (Full Range)	**1.00 (0.417 to 4.23)**	**1.06 (0.417 to 4.08)**

No statistical analysis provided for Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, Tmax

4. Primary: Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis,Cmax [Time Frame: Day 4 or 8]

Measure Type	Primary
Measure Title	Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis,Cmax
Measure Description	Cmax defined as peak concentration.
Time Frame	Day 4 or 8
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.
All-Subjects-Pharmacokinetically-Evaluable Group defined as all subjects for which at least one pharmacokinetic parameter could be calculated and who did not have any protocol violations interfering with pharmacokinetics.

Reporting Groups

	Description
Asenapine 5mg BID Day 4	Pharmacokinetic parameter of asepanine for Day 4.
Asenapine 10mg BID Day 8	Pharmacokinetic parameter of asepanine for Day 8.

Measured Values

	Asenapine 5mg BID Day 4	Asenapine 10mg BID Day 8
Number of Participants Analyzed [units: participants]	**87**	**60**
Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis,Cmax [units: ng/mL] Mean (Standard Deviation)	**6.01 (3.89)**	**10.3 (6.71)**

No statistical analysis provided for Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis,Cmax

5. Primary: Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis , Dn-Cmax [Time Frame: Day 4 or 8]

Measure Type	Primary
Measure Title	Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis , Dn-Cmax
Measure Description	dn-Cmax is defined as dose normalized peak concentration.
Time Frame	Day 4 or 8
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.
All-Subjects-Pharmacokinetically-Evaluable Group defined as all subjects for which at least one pharmacokinetic parameter could be calculated and who did not have any protocol violations interfering with pharmacokinetics.

Reporting Groups

	Description
Asenapine 5mg BID Day 4	Pharmacokinetic parameter of asepanine for Day 4.
Asenapine 10mg BID Day 8	Pharmacokinetic parameter of asepanine for Day 8.

Measured Values

	Asenapine 5mg BID Day 4	**Asenapine 10mg BID Day 8**
Number of Participants Analyzed [units: participants]	**87**	**60**
Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis , Dn-Cmax [units: ng/mL/mg] Mean (Standard Deviation)	**1.20 (0.778)**	**1.03 (0.671)**

No statistical analysis provided for Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis , Dn-Cmax

6. Primary: Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, Cmin [Time Frame: Day 4 or 8]

Measure Type	Primary
Measure Title	Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, Cmin
Measure Description	Cmin defined as pre-dose concentration.
Time Frame	Day 4 or 8
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.

All-Subjects-Pharmacokinetically-Evaluable Group defined as all subjects for which at least one pharmacokinetic parameter could be calculated and who did not have any protocol violations interfering with pharmacokinetics.

Reporting Groups

	Description
Asenapine 5mg BID Day 4	Pharmacokinetic parameters of asepanine for Day 4.
Asenapine 10mg BID Day 8	Pharmacokinetic parameters of asepanine for Day 8.

Measured Values

	Asenapine 5mg BID Day 4	Asenapine 10mg BID Day 8
Number of Participants Analyzed [units: participants]	**86**	**60**
Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, Cmin [units: ng/mL] Mean (Standard Deviation)	**2.28 (1.87)**	**4.06 (2.70)**

No statistical analysis provided for Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, Cmin

7. Primary: Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, AUC 0-12 [Time Frame: Day 4 or 8]

Measure Type	Primary
Measure Title	Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, AUC 0-12
Measure Description	AUC 0-12 defined as area-under-the-curve from zero to time point 12 hours.
Time Frame	Day 4 or 8
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.
All-Subjects-Pharmacokinetically-Evaluable Group defined as all subjects for which at least one pharmacokinetic parameter could be calculated and who did not have any protocol violations interfering with pharmacokinetics.

Reporting Groups

	Description
Asenapine 5mg BID Day 4	Pharmacokinetic parameter of asenapine for Day 4.
Asenapine 10mg BID Day 8	Pharmacokinetic parameter of asenapine for Day 8.

Measured Values

	Asenapine 5mg BID Day 4	Asenapine 10mg BID Day 8

Number of Participants Analyzed [units: participants]	**87**	**60**
Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, AUC 0-12 [units: ng*h/mL] Mean (Standard Deviation)	**38.6 (21.1)**	**70.3 (41.8)**

No statistical analysis provided for Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, AUC 0-12

8. Primary: Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, Dn-AUC 0-12 [Time Frame: Day 4 or 8]

Measure Type	Primary
Measure Title	Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, Dn-AUC 0-12
Measure Description	dn-AUC 0-12 defined as dose-normalized area-under-the-curve from zero to time point 12 hours.
Time Frame	Day 4 or 8
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.
All-Subjects-Pharmacokinetically-Evaluable Group defined as all subjects for which at least one pharmacokinetic parameter could be calculated and who did not have any protocol violations interfering with pharmacokinetics.

Reporting Groups

	Description
Asenapine 5mg BID Day 4	Pharmacokinetic parameter of asenapine for Day 4.
Asenapine 10mg BID Day 8	Pharmacokinetic parameter of asenapine for Day 8.

Measured Values

	Asenapine 5mg BID Day 4	**Asenapine 10mg BID Day 8**
Number of Participants Analyzed [units: participants]	**87**	**60**
Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, Dn-AUC 0-12 [units: ng*h/mL/mg] Mean (Standard Deviation)	**7.72 (4.22)**	**7.03 (4.18)**

No statistical analysis provided for Pharmacokinetics of Asenapine up to Doses of 10 mg BID in Elderly Subjects With Psychosis, Dn-AUC 0-12

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Asenapine 2-10mg BID	No text entered.
Asenapine 5-10mg BID	No text entered.

Serious Adverse Events

	Asenapine 2-10mg BID	Asenapine 5-10mg BID
Total, serious adverse events		
# participants affected / at risk	**6/61 (9.84%)**	**3/61 (4.92%)**
Cardiac disorders		
Cardio-respiratory arrest † 1		
# participants affected / at risk	**1/61 (1.64%)**	**0/61 (0.00%)**
# events	**1**	**0**
Ventricular extrasystoles † 1		
# participants affected / at risk	**0/61 (0.00%)**	**1/61 (1.64%)**
# events	**0**	**1**
Injury, poisoning and procedural complications		
Fall † 1		
# participants affected / at risk	**1/61 (1.64%)**	**0/61 (0.00%)**
# events	**1**	**0**
Hip fracture † 1		
# participants affected / at risk	**1/61 (1.64%)**	**0/61 (0.00%)**
# events	**1**	**0**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Metastases to pleura † 1		
# participants affected / at risk	**1/61 (1.64%)**	**0/61 (0.00%)**
# events	**1**	**0**
Nervous system disorders		
Extrapyramidal disorder † 1		
# participants affected / at risk	**1/61 (1.64%)**	**0/61 (0.00%)**
# events	**1**	**0**
Psychiatric disorders		
Mania † 1		
# participants affected / at risk	**0/61 (0.00%)**	**1/61 (1.64%)**

# events	0	1
Mental status changes † 1		
# participants affected / at risk	1/61 (1.64%)	0/61 (0.00%)
# events	1	0
Psychotic disorder † 1		
# participants affected / at risk	1/61 (1.64%)	0/61 (0.00%)
# events	1	0
Schizophrenia † 1		
# participants affected / at risk	0/61 (0.00%)	1/61 (1.64%)
# events	0	1
Renal and urinary disorders		
Azotaemia † 1		
# participants affected / at risk	1/61 (1.64%)	0/61 (0.00%)
# events	1	0

† Events were collected by systematic assessment
1 Term from vocabulary, 10.1

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
Asenapine 2-10mg BID	No text entered.
Asenapine 5-10mg BID	No text entered.

Other Adverse Events

	Asenapine 2-10mg BID	Asenapine 5-10mg BID
Total, other (not including serious) adverse events		
# participants affected / at risk	21/61 (34.43%)	21/61 (34.43%)
General disorders		
Asthenia † 1		
# participants affected / at risk	4/61 (6.56%)	2/61 (3.28%)

# events	4	2
Infections and infestations		
Urinary tract infection † 1		
# participants affected / at risk	4/61 (6.56%)	0/61 (0.00%)
# events	4	0
Investigations		
Blood pressure increased † 1		
# participants affected / at risk	0/61 (0.00%)	5/61 (8.20%)
# events	0	7
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	4/61 (6.56%)	2/61 (3.28%)
# events	4	3
Headache † 1		
# participants affected / at risk	4/61 (6.56%)	4/61 (6.56%)
# events	4	4
Parkinsonism † 1		
# participants affected / at risk	1/61 (1.64%)	5/61 (8.20%)
# events	1	6
Somnolence † 1		
# participants affected / at risk	5/61 (8.20%)	3/61 (4.92%)
# events	6	5
Psychiatric disorders		
Anxiety † 1		
# participants affected / at risk	0/61 (0.00%)	4/61 (6.56%)
# events	0	4
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	7/61 (11.48%)	3/61 (4.92%)
# events	11	3

† Events were collected by systematic assessment
1 Term from vocabulary, 10.1

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

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:** Institution will provide manuscripts, abstracts, or the full text of any other intended disclosure to the sponsor at least 30 days prior to submission for publication or other disclosure. If any patent action is required to protect intellectual property rights, Institution agrees to delay the disclosure for a period not to exceed and additional 60 days. Institution will, on request, remove any previously undisclosed Confidential Information (other than study results) before disclosure.

Results Point of Contact:

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

Publications of Results:

Dubovsky SL, Frobose C, Phiri P, de Greef R, Panagides J. Short-term safety and pharmacokinetic profile of asenapine in older patients with psychosis. Int J Geriatr Psychiatry. 2012 May;27(5):472-82. doi: 10.1002/gps.2737. Epub 2011 Jul 13.

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Other Study ID Numbers:	P05717 A7501021
Study First Received:	January 23, 2006
Results First Received:	August 12, 2010
Last Updated:	February 20, 2015
Health Authority:	United States: Food and Drug Administration

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