A Study of the Safety and Efficacy of MK-0773 in Women With Sarcopenia (Loss of Muscle Mass)(MK-0773-005)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00529659

First received: September 11, 2007
Last updated: January 29, 2015
Last verified: January 2015
History of Changes

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

Purpose

A study to evaluate the safety, tolerability, and efficacy of MK-0773 in women with sarcopenia (loss of muscle mass).

Condition	Intervention	Phase
Sarcopenia	Drug: Comparator: MK-0773 Drug: Comparator: Placebo	Phase 2

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

Official Title: A Phase IIa Randomized, Placebo-Controlled Clinical Trial to Study the Efficacy and Safety of MK-0773 in Patients With Sarcopenia

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

Primary Outcome Measures:

- Change From Baseline in Participant Lean Body Mass [Time Frame: Baseline, Month 6] [Designated as safety issue: No]
- Change From Baseline in Bilateral Leg Press (BLP) Measurement [Time Frame: Baseline, Month 6] [Designated as safety issue: No]

  BLP measurements were obtained with the participant sitting on the BLP exercise machine with flexed hips and knees. The participant held the handgrips with hips flexion and knees bent at a 90 degree angle and feet placed evenly on the footpad with heels placed approximately shoulder width apart. Participants were asked to slowly push the footpad forward, while keeping the knees slightly flexed, and bend back again slowly for one repetition. The BLP procedure measures the maximum amount of weight that the patient can push through his or her full range of motion one time.

Secondary Outcome Measures:

- Change From Baseline in Participant Short Physical Performance Battery (SPPB) [Time Frame: Baseline, Month 6] [Designated as safety issue: No]

  The Short Physical Performance Battery (SPPB) is an objective assessment tool for evaluating lower extremity functioning in older persons. The SPPB consists of 3 types of physical maneuvers: balance test, speed gait test, and chair stand test. Results from each maneuvers test are scored on a scale of 0 to 4, with an increasing composite score indicating an improved function level. The total maximum score of SPPB is 12.

- Change From Baseline in Participant Gait Speed [Time Frame: Baseline, Month 6] [Designated as safety issue: No]
- Change From Baseline in Stair Climbing Power [Time Frame: Baseline, Month 6] [Designated as safety issue: No]

  Stair-climbing power is an alternate measure of lower extremity muscle strength. Participants were asked to climb a standardized 4-step flight of stairs. The study coordinator timed how long it took the participant to walk up the stairs as quickly as possible. The test starts when the tester says "go" and ends when both of the patient's feet are flat on the platform area at the top of the staircase. Participants were permitted to use the railing, and/or an assistive device, if needed. Stair climbing power was calculated as = participant weight × gravity constant × height of stairs / time.

- Change From Baseline in Activity Measure for Post Acute Care (AM-PAC) Physical Movement Score [Time Frame: Baseline, Month 6] [Designated as safety issue: No]

  The Activity Measure for Post Acute Care (AM-PAC) measures function in three domains: basic mobility, daily activities, and applied cognitive function. AM-PAC scores in each functional domain have a mean of 50 with a standard deviation of 10 and scores are distributed along a continuum of function. The AM-PAC tracks outcomes as a participant progresses across an episode of care with higher scores indicating an improved level of functioning.

Enrollment:	170
Study Start Date:	October 2007
Study Completion Date:	October 2009
Primary Completion Date:	October 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: MK-0773 MK-0773	Drug: Comparator: MK-0773 MK-0773 50 mg tablets twice daily, 6 month treatment period
Placebo Comparator: Placebo Placebo	Drug: Comparator: Placebo Placebo tablets twice daily, 6 month treatment period

Eligibility

Ages Eligible for Study:	65 Years and older
Genders Eligible for Study:	Female
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patient is a woman who is 65 years of age or older
- Patient's lean body mass is at least 1 standard deviation below the mean of a healthy young adult population
- Patient has difficulty climbing 10 steps or walking outside on level ground for 1/4 mile without resting or Activity Measure for Post Acute Care (AM-PAC)<66

Exclusion Criteria:

- Patient has serious neurological, rheumatologic, cardiac, respiratory, kidney, psychiatric conditions
- Patient has a history of certain types of cancer

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.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00529659

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Papanicolaou DA, Ather SN, Zhu H, Zhou Y, Lutkiewicz J, Scott BB, Chandler J. A phase IIA randomized, placebo-controlled clinical trial to study the efficacy and safety of the selective androgen receptor modulator (SARM), MK-0773 in female participants with sarcopenia. J Nutr Health Aging. 2013;17(6):533-43. doi: 10.1007/s12603-013-0335-x.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00529659 History of Changes
Other Study ID Numbers:	0773-005 2007_532
Study First Received:	September 11, 2007
Results First Received:	April 6, 2012
Last Updated:	January 29, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
Sarcopenia (loss of muscle mass)

Additional relevant MeSH terms:

Sarcopenia	Neurologic Manifestations
Atrophy	Neuromuscular Manifestations
Muscular Atrophy	Pathological Conditions, Anatomical
Nervous System Diseases	Signs and Symptoms

ClinicalTrials.gov processed this record on April 14, 2016

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK

A Study of the Safety and Efficacy of MK-0773 in Women With Sarcopenia (Loss of Muscle Mass)(MK-0773-005)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00529659

First received: September 11, 2007
Last updated: January 29, 2015
Last verified: January 2015
History of Changes

Results First Received: April 6, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Sarcopenia
Interventions:	Drug: Comparator: MK-0773 Drug: Comparator: Placebo

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
Participants were randomized from 28 sites (2 sites in Mexico, 10 sites in South America, 8 sites in Europe, 5 sites in Asia Pacific, and 3 sites in South Africa).

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
After a 2-week placebo run-in period, patients were randomized in a 1:1 ratio to receive treatment with either oral MK-0773 50 mg twice daily or matching placebo.

Reporting Groups

	Description
MK-0773	MK-0773 was administered orally twice daily (BID) at a dose of 50 mg.
Placebo	Placebo administered orally twice daily.

Participant Flow: Overall Study

	MK-0773	Placebo
STARTED	**81**	**89**
COMPLETED	**70**	**66**
NOT COMPLETED	**11**	**23**
Adverse Event	**8**	**7**
Lost to Follow-up	**0**	**2**
Physician Decision	**0**	**2**
Protocol Violation	**2**	**6**
Withdrawal by Subject	**1**	**6**

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
MK-0773	MK-0773 was administered orally twice daily (BID) at a dose of 50 mg.
Placebo	Placebo administered orally twice daily.
Total	Total of all reporting groups

Baseline Measures

	MK-0773	Placebo	Total
Number of Participants [units: participants]	**81**	**89**	**170**
Age [units: years] Mean (Standard Deviation)	**75.0 (6.7)**	**76.8 (7.1)**	**75.9 (6.9)**

Gender [units: participants]			
Female	81	89	170
Male	0	0	0

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Participant Lean Body Mass [Time Frame: Baseline, Month 6]

Measure Type	Primary
Measure Title	Change From Baseline in Participant Lean Body Mass
Measure Description	No text entered.
Time Frame	Baseline, Month 6
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.
The full analysis set (FAS) included all participants that received at least one dose of the study therapy and had a post-randomization measurement of lean body mass.

Reporting Groups

	Description
MK-0773	MK-0773 was administered orally twice daily (BID) at a dose of 50 mg.
Placebo	Placebo administered orally twice daily.

Measured Values

	MK-0773	Placebo
Number of Participants Analyzed [units: participants]	65	60
Change From Baseline in Participant Lean Body Mass [units: kg] Mean (Standard Deviation)	1.26 (1.09)	0.29 (1.29)

No statistical analysis provided for Change From Baseline in Participant Lean Body Mass

2. Primary: Change From Baseline in Bilateral Leg Press (BLP) Measurement [Time Frame: Baseline, Month 6]

Measure Type	Primary
Measure Title	Change From Baseline in Bilateral Leg Press (BLP) Measurement
Measure Description	BLP measurements were obtained with the participant sitting on the BLP exercise machine with flexed hips and knees.

	The participant held the handgrips with hips flexion and knees bent at a 90 degree angle and feet placed evenly on the footpad with heels placed approximately shoulder width apart. Participants were asked to slowly push the footpad forward, while keeping the knees slightly flexed, and bend back again slowly for one repetition. The BLP procedure measures the maximum amount of weight that the patient can push through his or her full range of motion one time.
Time Frame	Baseline, Month 6
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.
N = Number of participants with at least one non-missing measurement at the time point.

Reporting Groups

	Description
MK-0773	MK-0773 was administered orally twice daily (BID) at a dose of 50 mg.
Placebo	Placebo administered orally twice daily.

Measured Values

	MK-0773	**Placebo**
Number of Participants Analyzed [units: participants]	**66**	**63**
Change From Baseline in Bilateral Leg Press (BLP) Measurement [units: lbs] Mean (Standard Deviation)	**17.42 (26.04)**	**15.95 (27.84)**

No statistical analysis provided for Change From Baseline in Bilateral Leg Press (BLP) Measurement

3. Secondary: Change From Baseline in Participant Short Physical Performance Battery (SPPB) [Time Frame: Baseline, Month 6]

Measure Type	Secondary
Measure Title	Change From Baseline in Participant Short Physical Performance Battery (SPPB)
Measure Description	The Short Physical Performance Battery (SPPB) is an objective assessment tool for evaluating lower extremity functioning in older persons. The SPPB consists of 3 types of physical maneuvers: balance test, speed gait test, and chair stand test. Results from each maneuvers test are scored on a scale of 0 to 4, with an increasing composite score indicating an improved function level. The total maximum score of SPPB is 12.
Time Frame	Baseline, Month 6
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.
N = Number of participants with at least one non-missing measurement at the time point.

Reporting Groups

	Description
MK-0773	MK-0773 was administered orally twice daily (BID) at a dose of 50 mg.
Placebo	Placebo administered orally twice daily.

Measured Values

	MK-0773	Placebo
Number of Participants Analyzed [units: participants]	**66**	**63**
Change From Baseline in Participant Short Physical Performance Battery (SPPB) [units: Score on a Scale] Mean (Standard Deviation)	**0.92 (1.63)**	**0.88 (1.60)**

No statistical analysis provided for Change From Baseline in Participant Short Physical Performance Battery (SPPB)

4. Secondary: Change From Baseline in Participant Gait Speed [Time Frame: Baseline, Month 6]

Measure Type	Secondary
Measure Title	Change From Baseline in Participant Gait Speed
Measure Description	No text entered.
Time Frame	Baseline, Month 6
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.
N = Number of participants with at least one non-missing measurement at the time point.

Reporting Groups

	Description
MK-0773	MK-0773 was administered orally twice daily (BID) at a dose of 50 mg.
Placebo	Placebo administered orally twice daily.

Measured Values

	MK-0773	Placebo
Number of Participants Analyzed [units: participants]	**66**	**63**
Change From Baseline in Participant Gait Speed [units: cm/sec] Mean (Standard Deviation)	**6.24 (17.65)**	**8.91 (15.05)**

No statistical analysis provided for Change From Baseline in Participant Gait Speed

5. Secondary: Change From Baseline in Stair Climbing Power [Time Frame: Baseline, Month 6]

Measure Type	Secondary
Measure Title	Change From Baseline in Stair Climbing Power
Measure Description	Stair-climbing power is an alternate measure of lower extremity muscle strength. Participants were asked to climb a standardized 4-step flight of stairs. The study coordinator timed how long it took the participant to walk up the stairs as quickly as possible. The test starts when the tester says "go" and ends when both of the patient's feet are flat on the platform area at the top of the staircase. Participants were permitted to use the railing, and/or an assistive device, if needed. Stair climbing power was calculated as = participant weight × gravity constant × height of stairs / time.
Time Frame	Baseline, Month 6
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.
The FAS included all participants that received at least one dose of the study therapy and had a post-randomization stair climbing power measurement.

Reporting Groups

	Description
MK-0773	MK-0773 was administered orally twice daily (BID) at a dose of 50 mg.
Placebo	Placebo administered orally twice daily.

Measured Values

	MK-0773	**Placebo**
Number of Participants Analyzed [units: participants]	**65**	**63**
Change From Baseline in Stair Climbing Power [units: watts] Mean (Standard Deviation)	**19.68 (23.85)**	**14.98 (20.71)**

No statistical analysis provided for Change From Baseline in Stair Climbing Power

6. Secondary: Change From Baseline in Activity Measure for Post Acute Care (AM-PAC) Physical Movement Score [Time Frame: Baseline, Month 6]

Measure Type	Secondary
Measure Title	Change From Baseline in Activity Measure for Post Acute Care (AM-PAC) Physical Movement Score
Measure Description	The Activity Measure for Post Acute Care (AM-PAC) measures function in three domains: basic mobility, daily activities, and applied cognitive function. AM-PAC scores in each functional domain have a mean of 50 with a standard deviation of 10 and scores are distributed along a continuum of function. The AM-PAC tracks outcomes as a participant progresses across an episode of care with higher scores indicating an improved level of functioning.
Time Frame	Baseline, Month 6

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.
N = Number of patient with at least one non-missing measurement at the time point.

Reporting Groups

	Description
MK-0773	MK-0773 was administered orally twice daily (BID) at a dose of 50 mg.
Placebo	Placebo administered orally twice daily.

Measured Values

	MK-0773	Placebo
Number of Participants Analyzed [units: participants]	**65**	**63**
Change From Baseline in Activity Measure for Post Acute Care (AM-PAC) Physical Movement Score [units: Score on a Scale] Mean (Standard Deviation)		
Baseline	**59.79 (6.29)**	**59.13 (5.28)**
Change from Baseline	**2.52 (4.98)**	**2.38 (4.55)**

No statistical analysis provided for Change From Baseline in Activity Measure for Post Acute Care (AM-PAC) Physical Movement Score

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
MK-0773	MK-0773 was administered orally twice daily (BID) at a dose of 50 mg.
Placebo	Placebo administered orally twice daily.

Serious Adverse Events

	MK-0773	Placebo
Total, serious adverse events		

# participants affected / at risk	12/81 (14.81%)	9/89 (10.11%)
Cardiac disorders		
Acute myocardial infarction [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Aortic valve stenosis [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Cardiac failure [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Cardiac failure congestive [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Myocardial infarction [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Supraventricular tachycardia [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Gastrointestinal disorders		
Abdominal distention [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Abdominal pain upper [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Constipation [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Pancreatic mass [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
General disorders		
Death [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Infections and infestations		
Lower respiratory tract infection [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Injury, poisoning and procedural complications		
Humerus fracture [1]		

# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Lower limb fracture [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Medical device complication [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Investigations		
Alanine aminotransferase increased [1]		
# participants affected / at risk	2/81 (2.47%)	0/89 (0.00%)
# events	2	0
Aspartate aminotransferase increased [1]		
# participants affected / at risk	2/81 (2.47%)	0/89 (0.00%)
# events	2	0
Transaminases increased [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Breast cancer [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Oesophageal carcinoma [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Nervous system disorders		
Ischaemic stroke [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Transient ischaemic attack [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Respiratory, thoracic and mediastinal disorders		
Pleural effusion [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Vascular disorders		
Deep vein thrombosis [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Hypertension [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0

1 Term from vocabulary, MedDRA (10.0)

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	0%

Reporting Groups

	Description
MK-0773	MK-0773 was administered orally twice daily (BID) at a dose of 50 mg.
Placebo	Placebo administered orally twice daily.

Other Adverse Events

	MK-0773	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	**50/81 (61.73%)**	**52/89 (58.43%)**
Blood and lymphatic system disorders		
Normochromic normocytic anaemia [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Cardiac disorders		
Acute myocardial infarction [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Aortic valve stenosis [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Atrial fibrillation [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Cardiac failure [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Cardiac failure congestive [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**

Hypertensive cardiomyopathy [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Myocardial infarction [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Palpitations [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Subendocardial ischaemia [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Supraventricular extrasystoles [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Supraventricular tachycardia [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Ear and labyrinth disorders		
Inner ear disorder [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Endocrine disorders		
Addison's disease [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Hypopituitarism [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Hypothyroidism [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Eye disorders		
Cataract [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Conjunctivitis [1]		
# participants affected / at risk	**1/81 (1.23%)**	**1/89 (1.12%)**
# events	**1**	**1**
Gastrointestinal disorders		
Abdominal distension [1]		
# participants affected / at risk	**1/81 (1.23%)**	**1/89 (1.12%)**
# events	**1**	**1**
Abdominal pain [1]		

# participants affected / at risk	1/81 (1.23%)	1/89 (1.12%)
# events	1	1
Abdominal pain upper [1]		
# participants affected / at risk	3/81 (3.70%)	0/89 (0.00%)
# events	3	0
Anorectal discomfort [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Colitis [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Constipation [1]		
# participants affected / at risk	3/81 (3.70%)	3/89 (3.37%)
# events	3	3
Dental caries [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Diarrhoea [1]		
# participants affected / at risk	5/81 (6.17%)	3/89 (3.37%)
# events	5	3
Dyspepsia [1]		
# participants affected / at risk	2/81 (2.47%)	0/89 (0.00%)
# events	2	0
Flatulence [1]		
# participants affected / at risk	1/81 (1.23%)	1/89 (1.12%)
# events	1	1
Food poisoning [1]		
# participants affected / at risk	1/81 (1.23%)	1/89 (1.12%)
# events	1	1
Gastrooesophageal reflux disease [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Irritable bowel syndrome [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Nausea [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Pancreatic mass [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Toothache [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Vomiting [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)

# events	0	1
General disorders		
Gastritis [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Asthenia [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Death [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Discomfort [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Face oedema [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Fatigue [1]		
# participants affected / at risk	2/81 (2.47%)	0/89 (0.00%)
# events	2	0
Gait disturbance [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Influenza like illness [1]		
# participants affected / at risk	6/81 (7.41%)	2/89 (2.25%)
# events	6	2
Malaise [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Oedema peripheral [1]		
# participants affected / at risk	2/81 (2.47%)	2/89 (2.25%)
# events	2	2
Pyrexia [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Immune system disorders		
Hypersensitivity [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Infections and infestations		
Bronchitis [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Bronchopneumonia [1]		

# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Cellulitis [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Folliculitis [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Gastroenteritis [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Gastroenteritis viral [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Herpes zoster [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Influenza [1]		
# participants affected / at risk	1/81 (1.23%)	2/89 (2.25%)
# events	1	2
Localised infection [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Lower respiratory tract infection [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Nasopharyngitis [1]		
# participants affected / at risk	1/81 (1.23%)	1/89 (1.12%)
# events	1	1
Oral herpes [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Pneumonia [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Tooth abscess [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Upper respiratory tract infection [1]		
# participants affected / at risk	0/81 (0.00%)	3/89 (3.37%)
# events	0	3
Urinary tract infection [1]		
# participants affected / at risk	3/81 (3.70%)	2/89 (2.25%)
# events	3	2
Injury, poisoning and procedural complications		

Contusion [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Fall [1]		
# participants affected / at risk	**1/81 (1.23%)**	**3/89 (3.37%)**
# events	**1**	**3**
Forearm fracture [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Head injury [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Humerus fracture [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Joint dislocation [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Joint injury [1]		
# participants affected / at risk	**1/81 (1.23%)**	**1/89 (1.12%)**
# events	**1**	**1**
Joint sprain [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Limb injury [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Lower limb fracture [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Medical device complication [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Pelvic fracture [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Radius fracture [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Ulna fracture [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Upper limb fracture [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Investigations		

Alanine aminotransferase increased [1]		
# participants affected / at risk	**8/81 (9.88%)**	**1/89 (1.12%)**
# events	**8**	**1**
Aspartate aminotransferase increased [1]		
# participants affected / at risk	**7/81 (8.64%)**	**1/89 (1.12%)**
# events	**7**	**1**
Blood cortisol decreased [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Blood sodium decreased [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Electrocardiogram T wave inversion [1]		
# participants affected / at risk	**1/81 (1.23%)**	**1/89 (1.12%)**
# events	**1**	**1**
Haematocrit decreased [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Haematocrit increased [1]		
# participants affected / at risk	**8/81 (9.88%)**	**2/89 (2.25%)**
# events	**8**	**2**
Haemoglobin decreased [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Haemoglobin increased [1]		
# participants affected / at risk	**3/81 (3.70%)**	**1/89 (1.12%)**
# events	**3**	**1**
High density lipoprotein decreased [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Neutrophil count increased [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Platelet count increased [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Transaminases increased [1]		
# participants affected / at risk	**2/81 (2.47%)**	**1/89 (1.12%)**
# events	**2**	**1**
Weight increased [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
White blood cell count increased [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**

Metabolism and nutrition disorders		
Decreased appetite [1]		
# participants affected / at risk	**2/81 (2.47%)**	**0/89 (0.00%)**
# events	**2**	**0**
Hypoglycaemia [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Increased appetite [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Musculoskeletal and connective tissue disorders		
Arthralgia [1]		
# participants affected / at risk	**3/81 (3.70%)**	**2/89 (2.25%)**
# events	**3**	**2**
Back pain [1]		
# participants affected / at risk	**3/81 (3.70%)**	**1/89 (1.12%)**
# events	**3**	**1**
Bone pain [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Bursitis [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Costochondritis [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Fibromyalgia [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Joint swelling [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**
Muscle spasms [1]		
# participants affected / at risk	**0/81 (0.00%)**	**2/89 (2.25%)**
# events	**0**	**2**
Musculoskeletal pain [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Musculoskeletal stiffness [1]		
# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Myalgia [1]		
# participants affected / at risk	**2/81 (2.47%)**	**0/89 (0.00%)**
# events	**2**	**0**
Neck pain [1]		

# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Osteoarthritis [1]		
# participants affected / at risk	0/81 (0.00%)	2/89 (2.25%)
# events	0	2
Osteopenia [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Pain in extremity [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Breast cancer [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Oesophageal carcinoma [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Nervous system disorders		
Oesophageal carcinoma [1]		
# participants affected / at risk	2/81 (2.47%)	1/89 (1.12%)
# events	2	1
Dysstasia [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Essential tremor [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Headache [1]		
# participants affected / at risk	2/81 (2.47%)	3/89 (3.37%)
# events	2	3
Ischaemic stroke [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Lethargy [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Paraesthesia [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Sciatica [1]		
# participants affected / at risk	0/81 (0.00%)	2/89 (2.25%)
# events	0	2
Transient ischaemic attack [1]		

# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Psychiatric disorders		
Depression [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Insomnia [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Reproductive system and breast disorders		
Breast cyst [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Respiratory, thoracic and mediastinal disorders		
Cough [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Dyspnoea [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Pleural effusion [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Skin and subcutaneous tissue disorders		
Acne [1]		
# participants affected / at risk	3/81 (3.70%)	2/89 (2.25%)
# events	3	2
Alopecia [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Rash macular [1]		
# participants affected / at risk	1/81 (1.23%)	0/89 (0.00%)
# events	1	0
Vascular disorders		
Deep vein thrombosis [1]		
# participants affected / at risk	0/81 (0.00%)	1/89 (1.12%)
# events	0	1
Haematoma [1]		
# participants affected / at risk	2/81 (2.47%)	0/89 (0.00%)
# events	2	0
Hypertension [1]		
# participants affected / at risk	2/81 (2.47%)	4/89 (4.49%)
# events	2	4
Hypotension [1]		

# participants affected / at risk	**0/81 (0.00%)**	**1/89 (1.12%)**
# events	**0**	**1**
Varicose ulceration [1]		
# participants affected / at risk	**1/81 (1.23%)**	**0/89 (0.00%)**
# events	**1**	**0**

1 Term from vocabulary, MedDRA (10.0)

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.

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:

Papanicolaou DA, Ather SN, Zhu H, Zhou Y, Lutkiewicz J, Scott BB, Chandler J. A phase IIA randomized, placebo-controlled clinical trial to study the efficacy and safety of the selective androgen receptor modulator (SARM), MK-0773 in female participants with sarcopenia. J Nutr Health Aging. 2013;17(6):533-43. doi: 10.1007/s12603-013-0335-x.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00529659 History of Changes
Other Study ID Numbers: 0773-005
2007_532
Study First Received: September 11, 2007
Results First Received: April 6, 2012

Last Updated:	January 29, 2015
Health Authority:	United States: Food and Drug Administration

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK