A Study of a Novel Investigational Drug in Rheumatoid Arthritis Patients (MK-0873-012)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00132769

First received: August 2, 2005
Last updated: July 29, 2015
Last verified: July 2015
History of Changes

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

Purpose

This study will look at whether this new drug is effective in the treatment of rheumatoid arthritis, and at whether it is safe and well-tolerated by participants with the disease.

Condition	Intervention	Phase
Rheumatoid Arthritis	Drug: MK-0873 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 Randomized, Placebo-Controlled, Parallel-Group, Double-Blind, 12-Week Study to Assess the Clinical Efficacy, Safety, and Tolerability of MK-0873 in Rheumatoid Arthritis

Resource links provided by NLM:

Genetics Home Reference related topics: rheumatoid arthritis

MedlinePlus related topics: Arthritis Rheumatoid Arthritis

U.S. FDA Resources

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

Primary Outcome Measures:

- Change From Baseline in Swollen Joint Count [Time Frame: Baseline and the average of Treatment Weeks 8, 10 and 12]

[Designated as safety issue: No]

Swollen joint count (SJC) was determined by assessing 66 joints (33 right side, 33 left side) for swelling using the following grading system: 0=Absent, 1=Detectable synovial thickening without loss of bony contours, 2=Loss of distinctiveness of bony contours, or 3=Bulging synovial proliferation with cystic characteristics. The total number of joints graded 1, 2, or 3 were then counted to yield the SJC. SJC ranged from 1-66, with increasing score indicating greater number of swollen joints. SJC was averaged over weeks 8, 10 and 12 to yield a Treatment Period Mean. Change from Baseline = Treatment Period Mean SJC - Baseline SJC.

Secondary Outcome Measures:

- Percentage of Participants With American College of Rheumatology 20% Response [ACR20] [Time Frame: Baseline and the average of Treatment Weeks 8, 10 and 12] [Designated as safety issue: No]

  Participants were categorized as meeting ACR20 criteria when they had at least 20% improvement from Baseline in tender and swollen joint counts, and improvement from Baseline in at least 3 of 5 of the following domains: Pain Visual Analog Scale (VAS), Patient Global Assessement, Physician Global Assessment, Patient Physical Function (Disability) Score and acute-phase reactant (Erythrocyte Sedimentation Rate [ESR] or C-Reactive Protein [CRP]). The average percentage of participants that met the ACR20 responder criteria over Treatment Weeks 8, 10 and 12 was calculated.

- Change From Baseline in Tender Joint Count [Time Frame: Baseline and the average of Treatment Weeks 8, 10 and 12] [Designated as safety issue: No]

  Tender joint count (TJC) was to be determined by assessing 68 joints (34 right side, 34 left side) for pain using the following grading system: 0=No pain, 1=Patient states that there is pain, 2=Patient states that there is pain and winces, or 3=Patient states that there is pain, winces, and withdraws. The total number of joints graded 1, 2, or 3 were then to be counted to yield the TJC. TJC ranges from 1-68, with increasing score indicating greater number of tender joints. TJC was to be averaged over weeks 8, 10, and 12 to yield a Treatment Period Mean. Change from Baseline = Treatment Period Mean TJC - Baseline TJC.

- Patient Global Assessment of Disease Activity [Time Frame: The average of Treatment Weeks 8, 10 and 12] [Designated as safety issue: No]

  At each clinic visit, participants were to assess disease activity using a 100 mm visual analog scale (VAS) in reponse to the question: "Considering all the ways your arthritis affects you, mark an (X) through the line for how well you are doing." The VAS ranges from "Very Well" (0) to "Very Poor" (100). The mean score at Treatment Weeks 8, 10 and 12 was calculated. A lower score indicates a better disease activity.

- Investigator Global Assessment of Disease Activity [Time Frame: Treatment Week 12] [Designated as safety issue: No]

  At each clinic visit, the Investigator was to make a global assessment of participant disease activity on a 5-point Likert scale with grading as follows: 1=Very well, 2=Well, 3=Fair, 4=Poor, or 5=Very poor (scale range: 1-5). A lower score indicates a more positive assessment of participant disease activity.

- Patient Global Assessment of Response to Therapy [Time Frame: Treatment Week 12] [Designated as safety issue: No]

  Participants were to rate their overall response to the study drug on a 5-point Likert scale with grading as follows: 0=None, 1=Poor, 2=Fair, 3=Good, or 4=Excellent (scale range: 0-4). A higher score indicates a more positive response to study drug.

- Health Assessment Questionnaire Disability Index [Time Frame: The average of Treatment Weeks 8, 10 and 12] [Designated as safety issue: No]

  The Stanford Health Assessment Questionnaire Disability Index assesses participant functional ability based on 20 questions in 8 categories of functioning: dressing, rising, eating, walking, hygiene, reach, grip, and usual activities. Responses range from 0=No disability to 3=Completely disabled. The score for each category subscale is the single response within the category with the highest score (greatest difficulty). The overall score for the Disability Index is the mean of the 8 category scores and also ranges from 0-3, with a lower score indicating less disability.

- Patient's Assessment of Pain [Time Frame: Treatment Week 12] [Designated as safety issue: No]

  At each clinic visit, participants were to assess their amount of pain due to arthritis during the previous 48 hours on a 100 mm visual analog scale (VAS) that ranged from "No pain" (0) to "Extreme pain" (100). A lower score indicates less pain.

- Ratio of On-treatment C-Reactive Protein to Baseline C-Reactive Protein [Time Frame: Baseline and the average of Treatment Weeks 8, 10 and 12] [Designated as safety issue: No]

  C-reactive protein levels rise in response to inflammation in the body. The ratio of On-treatment serum C-reative protein:Baseline serum C-reactive protein was calculated to determine a treatment effect. On-treatment C-reactive protein = the mean of serum C-reactive protein levels for Treatment Weeks 8, 10 and 12. A ratio of less than 1.0 is consistent with lower inflammation and was to be considered an improvement.

Enrollment:	106
Study Start Date:	January 2005
Study Completion Date:	November 2005
Primary Completion Date:	November 2005 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: MK-0873 MK-0873 1.25 mg twice daily for 12 weeks	Drug: MK-0873 MK-0873 1.25 mg twice daily for 12 weeks
Placebo Comparator: Placebo Matching placebo to MK-0873 1.25 mg twice daily for 12 weeks	Drug: Comparator: Placebo Matching placebo to MK-0873 1.25 mg twice daily for 12 weeks

Eligibility

Ages Eligible for Study:	18 Years to 65 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Rheumatoid arthritis, according to the American College of Rheumatology criteria, with active disease despite current medications
- Other criteria also apply

Exclusion Criteria:

- Other major illnesses
- Past history of certain other disorders
- Certain prohibited medications

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: NCT00132769

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00132769 History of Changes
Other Study ID Numbers:	0873-012 2005_029
Study First Received:	August 2, 2005
Results First Received:	October 7, 2013
Last Updated:	July 29, 2015
Health Authority:	Canada: Health Canada

Additional relevant MeSH terms:

Arthritis	Immune System Diseases

Arthritis, Rheumatoid
Autoimmune Diseases
Connective Tissue Diseases
Joint Diseases
Musculoskeletal Diseases
Rheumatic Diseases

ClinicalTrials.gov processed this record on April 14, 2016

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First received: August 2, 2005
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Last verified: July 2015
History of Changes

Results First Received: October 7, 2013

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:	Rheumatoid Arthritis
Interventions:	Drug: MK-0873 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
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

MK-0873	Participants receive MK-0873 1.25 mg twice daily for 12 weeks
Placebo	Participants receive matching placebo to MK-0873 twice daily for 12 weeks

Participant Flow: Overall Study

	MK-0873	Placebo
STARTED	**53**	**53**
COMPLETED	**42**	**42**
NOT COMPLETED	**11**	**11**
Withdrawal by Subject	**1**	**3**
Lack of Efficacy	**7**	**6**
Adverse Event	**2**	**1**
Protocol Violation	**1**	**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
MK-0873	Participants receive MK-0873 1.25 mg twice daily for 12 weeks
Placebo	Participants receive matching placebo to MK-0873 twice daily for 12 weeks
Total	Total of all reporting groups

Baseline Measures

	MK-0873	Placebo	Total
Number of Participants [units: participants]	**53**	**53**	**106**
Age [units: years] Mean (Standard Deviation)	**51.0 (9.30)**	**53.5 (8.99)**	**52.3 (9.19)**
Gender [units: participants]			
Female	**35**	**40**	**75**
Male	**18**	**13**	**31**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Swollen Joint Count [Time Frame: Baseline and the average of Treatment Weeks 8, 10 and 12]

Measure Type	Primary
Measure Title	Change From Baseline in Swollen Joint Count
Measure Description	Swollen joint count (SJC) was determined by assessing 66 joints (33 right side, 33 left side) for swelling using the following grading system: 0=Absent, 1=Detectable synovial thickening without loss of bony contours, 2=Loss of distinctiveness of bony contours, or 3=Bulging synovial proliferation with cystic characteristics. The total number of joints graded 1, 2, or 3 were then counted to yield the SJC. SJC ranged from 1-66, with increasing score indicating greater number of swollen joints. SJC was averaged over weeks 8, 10 and 12 to yield a Treatment Period Mean. Change from Baseline = Treatment Period Mean SJC - Baseline SJC.
Time Frame	Baseline and the average of Treatment Weeks 8, 10 and 12
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 All Patients Treated (APT) population consisted of all participants with a baseline and at least one postbaseline observation.

Reporting Groups

	Description
MK-0873	Participants receive MK-0873 1.25 mg twice daily for 12 weeks
Placebo	Participants receive matching placebo to MK-0873 twice daily for 12 weeks

Measured Values

	MK-0873	**Placebo**
Number of Participants Analyzed [units: participants]	**53**	**53**
Change From Baseline in Swollen Joint Count [units: score on a scale] Least Squares Mean (95% Confidence Interval)	**-7.20 (-9.54 to -4.86)**	**-8.68 (-10.97 to -6.39)**

Statistical Analysis 1 for Change From Baseline in Swollen Joint Count

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.278
Difference in LS Mean [4]	1.48
95% Confidence Interval	-1.21 to 4.18

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Percentage of Participants With American College of Rheumatology 20% Response [ACR20] [Time Frame: Baseline and the average of Treatment Weeks 8, 10 and 12]

Measure Type	Secondary
Measure Title	Percentage of Participants With American College of Rheumatology 20% Response [ACR20]
Measure Description	Participants were categorized as meeting ACR20 criteria when they had at least 20% improvement from Baseline in tender and swollen joint counts, and improvement from Baseline in at least 3 of 5 of the following domains: Pain Visual Analog Scale (VAS), Patient Global Assessement, Physician Global Assessment, Patient Physical Function (Disability) Score and acute-phase reactant (Erythrocyte Sedimentation Rate [ESR] or C-Reactive Protein [CRP]). The average percentage of participants that met the ACR20 responder criteria over Treatment Weeks 8, 10 and 12 was calculated.
Time Frame	Baseline and the average of Treatment Weeks 8, 10 and 12
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 APT population consisted of all participants with a baseline and at least one postbaseline observation.

Reporting Groups

	Description
MK-0873	Participants receive MK-0873 1.25 mg twice daily for 12 weeks
Placebo	Participants receive matching placebo to MK-0873 twice daily for 12 weeks

Measured Values

	MK-0873	**Placebo**
Number of Participants Analyzed [units: participants]	**53**	**53**
Percentage of Participants With American College of Rheumatology 20% Response [ACR20] [units: percentage of participants]	**39.62**	**45.28**

Statistical Analysis 1 for Percentage of Participants With American College of Rheumatology 20% Response [ACR20]

Groups [1]	All groups
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.543
Difference in Percent [4]	-5.66
95% Confidence Interval	-24.45 to 13.13

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

3. Secondary: Change From Baseline in Tender Joint Count [Time Frame: Baseline and the average of Treatment Weeks 8, 10 and 12]

Measure Type	Secondary
Measure Title	Change From Baseline in Tender Joint Count
Measure Description	Tender joint count (TJC) was to be determined by assessing 68 joints (34 right side, 34 left side) for pain using the following grading system: 0=No pain, 1=Patient states that there is pain, 2=Patient states that there is pain and winces, or 3=Patient states that there is pain, winces, and withdraws. The total number of joints graded 1, 2, or 3 were then to be counted to yield the TJC. TJC ranges from 1-68, with increasing score indicating greater number of tender joints. TJC was to be averaged over weeks 8, 10, and 12 to yield a Treatment Period Mean. Change from Baseline = Treatment Period Mean TJC - Baseline TJC.
Time Frame	Baseline and the average of Treatment Weeks 8, 10 and 12
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 additional analyses were performed if the primary (Swollen Joint Count) and major secondary (ACR20) outcome measures resulted in a p-value of >0.05.

Reporting Groups

	Description
MK-0873	Participants receive MK-0873 1.25 mg twice daily for 12 weeks
Placebo	Participants receive matching placebo to MK-0873 twice daily for 12 weeks

Measured Values

	MK-0873	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Change From Baseline in Tender Joint Count		

No statistical analysis provided for Change From Baseline in Tender Joint Count

4. Secondary: Patient Global Assessment of Disease Activity [Time Frame: The average of Treatment Weeks 8, 10 and 12]

Measure Type	Secondary
Measure Title	Patient Global Assessment of Disease Activity
Measure Description	At each clinic visit, participants were to assess disease activity using a 100 mm visual analog scale (VAS) in reponse to the question: “Considering all the ways your arthritis affects you, mark an (X) through the line for how well you are doing.” The VAS ranges from "Very Well" (0) to "Very Poor" (100). The mean score at Treatment Weeks 8, 10 and 12 was calculated. A lower score indicates a better disease activity.
Time Frame	The average of Treatment Weeks 8, 10 and 12
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 additional analyses were performed if the primary (Swollen Joint Count) and major secondary (ACR20) outcome measures resulted in a p-value of >0.05.

Reporting Groups

	Description
MK-0873	Participants receive MK-0873 1.25 mg twice daily for 12 weeks
Placebo	Participants receive matching placebo to MK-0873 twice daily for 12 weeks

Measured Values

	MK-0873	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Patient Global Assessment of Disease Activity		

No statistical analysis provided for Patient Global Assessment of Disease Activity

5. Secondary: Investigator Global Assessment of Disease Activity [Time Frame: Treatment Week 12]

Measure Type	Secondary

Measure Title	Investigator Global Assessment of Disease Activity
Measure Description	At each clinic visit, the Investigator was to make a global assessment of participant disease activity on a 5-point Likert scale with grading as follows: 1=Very well, 2=Well, 3=Fair, 4=Poor, or 5=Very poor (scale range: 1-5). A lower score indicates a more positive assessment of participant disease activity.
Time Frame	Treatment Week 12
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 additional analyses were performed if the primary (Swollen Joint Count) and major secondary (ACR20) outcome measures resulted in a p-value of >0.05.

Reporting Groups

	Description
MK-0873	Participants receive MK-0873 1.25 mg twice daily for 12 weeks
Placebo	Participants receive matching placebo to MK-0873 twice daily for 12 weeks

Measured Values

	MK-0873	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Investigator Global Assessment of Disease Activity		

No statistical analysis provided for Investigator Global Assessment of Disease Activity

6. Secondary: Patient Global Assessment of Response to Therapy [Time Frame: Treatment Week 12]

Measure Type	Secondary
Measure Title	Patient Global Assessment of Response to Therapy
Measure Description	Participants were to rate their overall response to the study drug on a 5-point Likert scale with grading as follows: 0=None, 1=Poor, 2=Fair, 3=Good, or 4=Excellent (scale range: 0-4). A higher score indicates a more positive response to study drug.
Time Frame	Treatment Week 12
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 additional analyses were performed if the primary (Swollen Joint Count) and major secondary (ACR20) outcome measures resulted in a p-value of >0.05.

Reporting Groups

	Description
MK-0873	Participants receive MK-0873 1.25 mg twice daily for 12 weeks
Placebo	Participants receive matching placebo to MK-0873 twice daily for 12 weeks

Measured Values

	MK-0873	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Patient Global Assessment of Response to Therapy		

No statistical analysis provided for Patient Global Assessment of Response to Therapy

7. Secondary: Health Assessment Questionnaire Disability Index [Time Frame: The average of Treatment Weeks 8, 10 and 12]

Measure Type	Secondary
Measure Title	Health Assessment Questionnaire Disability Index
Measure Description	The Stanford Health Assessment Questionnaire Disability Index assesses participant functional ability based on 20 questions in 8 categories of functioning: dressing, rising, eating, walking, hygiene, reach, grip, and usual activities. Responses range from 0=No disability to 3=Completely disabled. The score for each category subscale is the single response within the category with the highest score (greatest difficulty). The overall score for the Disability Index is the mean of the 8 category scores and also ranges from 0-3, with a lower score indicating less disability.
Time Frame	The average of Treatment Weeks 8, 10 and 12
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 additional analyses were performed if the primary (Swollen Joint Count) and major secondary (ACR20) outcome measures resulted in a p-value of >0.05.

Reporting Groups

	Description
MK-0873	Participants receive MK-0873 1.25 mg twice daily for 12 weeks
Placebo	Participants receive matching placebo to MK-0873 twice daily for 12 weeks

Measured Values

	MK-0873	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Health Assessment Questionnaire Disability Index		

No statistical analysis provided for Health Assessment Questionnaire Disability Index

8. Secondary: Patient's Assessment of Pain [Time Frame: Treatment Week 12]

Measure Type	Secondary
Measure Title	Patient's Assessment of Pain
Measure Description	At each clinic visit, participants were to assess their amount of pain due to arthritis during the previous 48 hours on a 100 mm visual analog scale (VAS) that ranged from "No pain" (0) to "Extreme pain" (100). A lower score indicates less pain.
Time Frame	Treatment Week 12
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 additional analyses were performed if the primary (Swollen Joint Count) and major secondary (ACR20) outcome measures resulted in a p-value of >0.05.

Reporting Groups

	Description
MK-0873	Participants receive MK-0873 1.25 mg twice daily for 12 weeks
Placebo	Participants receive matching placebo to MK-0873 twice daily for 12 weeks

Measured Values

	MK-0873	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Patient's Assessment of Pain		

No statistical analysis provided for Patient's Assessment of Pain

9. Secondary: Ratio of On-treatment C-Reactive Protein to Baseline C-Reactive Protein [Time Frame: Baseline and the average of Treatment Weeks 8, 10 and 12]

Measure Type	Secondary
Measure Title	Ratio of On-treatment C-Reactive Protein to Baseline C-Reactive Protein
Measure Description	C-reactive protein levels rise in response to inflammation in the body. The ratio of On-treatment serum C-reative protein:Baseline serum C-reactive protein was calculated to determine a treatment effect. On-treatment C-reactive protein = the mean of serum C-reactive protein levels for Treatment Weeks 8, 10 and 12. A ratio of less than 1.0 is consistent with lower inflammation and was to be considered an improvement.
Time Frame	Baseline and the average of Treatment Weeks 8, 10 and 12

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 APT population consisted of all participants with a baseline and at least one postbaseline observation.

Reporting Groups

	Description
MK-0873	Participants receive MK-0873 1.25 mg twice daily for 12 weeks
Placebo	Participants receive matching placebo to MK-0873 twice daily for 12 weeks

Measured Values

	MK-0873	**Placebo**
Number of Participants Analyzed [units: participants]	**53**	**53**
Ratio of On-treatment C-Reactive Protein to Baseline C-Reactive Protein [units: ratio] Least Squares Mean (95% Confidence Interval)	**0.90 (0.70 to 1.16)**	**1.08 (0.85 to 1.38)**

Statistical Analysis 1 for Ratio of On-treatment C-Reactive Protein to Baseline C-Reactive Protein

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.225
LS mean ratio between treatments [4]	0.84
95% Confidence Interval	0.63 to 1.12

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 4 weeks
Additional Description	The safety population consisted of all participants who took at least one dose of study drug.

Reporting Groups

	Description
MK-0873	Participants receive MK-0873 1.25 mg twice daily for 12 weeks
Placebo	Participants receive matching placebo to MK-0873 twice daily for 12 weeks

Serious Adverse Events

	MK-0873	Placebo
Total, serious adverse events		
# participants affected / at risk	**1/53 (1.89%)**	**2/53 (3.77%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Uterine Leiomyoma † 1		
# participants affected / at risk	**1/53 (1.89%)**	**0/53 (0.00%)**
Psychiatric disorders		
Mental Disorder † 1		
# participants affected / at risk	**0/53 (0.00%)**	**1/53 (1.89%)**
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	**0/53 (0.00%)**	**1/53 (1.89%)**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 8.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 4 weeks
Additional Description	The safety population consisted of all participants who took at least one dose of study drug.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
MK-0873	Participants receive MK-0873 1.25 mg twice daily for 12 weeks

Placebo	Participants receive matching placebo to MK-0873 twice daily for 12 weeks

Other Adverse Events

	MK-0873	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	**10/53 (18.87%)**	**4/53 (7.55%)**
Gastrointestinal disorders		
Diarrhoea † 1		
# participants affected / at risk	**6/53 (11.32%)**	**4/53 (7.55%)**
Musculoskeletal and connective tissue disorders		
Back pain † 1		
# participants affected / at risk	**4/53 (7.55%)**	**0/53 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 8.1

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:** The Sponsor must have the opportunity to review all proposed abstracts, manuscripts, or presentations regarding this study 60 days prior to submission for publication/presentation.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development

Organization: Merck Sharp & Dohme Corp.
phone: 1-800-672-6372
e-mail: ClinicalTrialsDisclosure@merck.com

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00132769 History of Changes
Other Study ID Numbers:	0873-012 2005_029 (Other Identifier: Telerex Study Number)</br>
Study First Received:	August 2, 2005
Results First Received:	October 7, 2013
Last Updated:	July 29, 2015
Health Authority:	Canada: Health Canada

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