Neutrophilic Asthma Study With Navarixin (MK-7123, SCH 527123) (MK-7123-017)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00632502

First received: February 29, 2008
Last updated: October 28, 2015
Last verified: October 2015
History of Changes

Purpose

4-Week Safety Study in Subjects with Neutrophilic Asthma

Condition	Intervention	Phase
Neutrophilic Asthma	Drug: Navarixin Drug: Placebo Drug: Rescue medication	Phase 2

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

Official Title: Safety of SCH 527123 in Subjects With Neutrophilic Asthma

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

Primary Outcome Measures:

- Number of Participants Who Maintained an Absolute Peripheral Blood Neutrophil Count >=1500/µL [Time Frame: Up to 4 weeks] [Designated as safety issue: Yes]

  Peripheral blood neutrophil counts were performed on Day 2 and Weeks 1, 2, 3, and 4 of the treatment period

Secondary Outcome Measures:

- Mean Change From Baseline in Sputum Absolute Neutrophil Count [Time Frame: Baseline and while on study drug (up to 4 weeks)] [Designated as safety issue: No]

Induced sputum samples were obtained at Baseline and at Weeks 2 and 4 of the treatment period. Samples were collected before study drug administration using the nebulizer method and sent to a central laboratory for analysis. An average was taken over all post-baseline samples collected no later than one day after the last dose of study drug.

- Mean Change From Baseline in Total Asthma Symptom Score [Time Frame: Baseline and Weeks 1, 2, 3, and 4] [Designated as safety issue: No]

  Total Asthma Symptom Score is the sum of individual symptoms of wheezing, coughing, and dyspnea assessed twice daily (morning and evening) and is recorded on a comment diary card. Each of the symptoms receives a daily score from 0 (none) to 3 (severe), averaged over the two daily assessments. The total score ranges from 0 to 9, with a lower score indicating less severe asthma symptoms.

- Change From Baseline in Post-Bronchodilator Forced Expiratory Volume in One Second (FEV1) [Time Frame: Baseline and up to 4 weeks] [Designated as safety issue: No]

  Spirometry was used to measure post-bronchodilator FEV1 at Baseline and before study drug administration at Weeks 1, 2, 3, and 4. Participants received 4 puffs of bronchodilator (salbutamol hydrofluoroalkane or equivalent) at 30-second intervals and spirometry was performed 30 minutes later. The mean change from baseline is based on the average change over all post-baseline assessments.

- Change From Baseline in Asthma Quality of Life Questionnaire With Standardized Activities (AQLQ[S]) [Time Frame: Baseline and up to 4 weeks] [Designated as safety issue: No]

  The AQLQ[S] was administered at Baseline and at Weeks 2 and 4. The assessment consists of a 32-item questionnaire covering 4 domains: symptoms, emotional functioning, impact of environmental stimuli, and activity limitation. Each item receives a score from 1 (worst, or most affected) to 7 (not at all affected). The score is the mean across all items, and ranges from 1 to 7. The mean change from baseline is based on the average change over all post-baseline assessments.

- Number of Participants With an Adverse Event (AE) [Time Frame: Up to 5 weeks] [Designated as safety issue: Yes]

  An AE is any untoward medical occurrence in a participant administered study drug which does not necessarily have a causal relationship with the treatment. AEs may include the onset of new illness and the exacerbation of pre-existing conditions.

- Number of Participants With an Electrocardiogram Adverse Event [Time Frame: Week 4] [Designated as safety issue: Yes]

  The endpoint measured was any electrocardiogram abnormality that was reported as an AE. An AE is any untoward medical occurrence in a participant administered study drug which does not necessarily have a causal relationship with the treatment. AEs may include the onset of new illness and the exacerbation of pre-existing conditions.

- Number of Participants With a Laboratory Adverse Event [Time Frame: Up to 5 weeks] [Designated as safety issue: Yes]

  The endpoint measured was any laboratory (hematology, blood chemistry, or urinalysis) abnormality that was reported as an AE. An AE is any untoward medical occurrence in a participant administered study drug which does not necessarily have a causal relationship with the treatment. AEs may include the onset of new illness and the exacerbation of pre-existing conditions.

- Number of Participants Who Discontinued the Study Because of an Adverse Event [Time Frame: Up to 5 weeks] [Designated as safety issue: Yes]

  An AE is any untoward medical occurrence in a participant administered study drug which does not necessarily have a causal relationship with the treatment. AEs may include the onset of new illness and the exacerbation of pre-existing conditions.

- Number of Participants Who Discontinued Treatment Because of an Adverse Event or a Protocol-defined Clinical Event [Time Frame: Up to 4 weeks] [Designated as safety issue: Yes]

  An AE is any untoward medical occurrence in a participant administered study drug which does not necessarily have a causal relationship with the treatment. AEs may include the onset of new illness and the exacerbation of pre-existing conditions. A protocol-defined clinical event is an asthma exacerbation requiring addition of or increase in systemic steroids, as determined by the investigator.

- Maximum Plasma Concentration of Navarixin (Cmax) [Time Frame: Week 1, 2, 3, and 4] [Designated as safety issue: No]

  Plasma samples were to be collected at baseline and up to 24 hours after dosing with navarixin at Weeks 1, 2, 3, and 4

Enrollment:	37
Study Start Date:	May 2008
Study Completion Date:	February 2009
Primary Completion Date:	February 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Navarixin Navarixin (MK-7123, SCH 527123) 30 mg capsule, to be taken by mouth once daily in the morning for 4 weeks	Drug: Navarixin Navarixin 30 mg capsule to be taken by mouth once daily in the morning for 4 weeks. Drug: Rescue medication Participant choice of short-acting beta-2 agonist (salbutamol/albuterol), anticholinergic, or combination medication as needed for asthma symptoms
Placebo Comparator: Placebo Placebo capsule to match navarixin, to be taken by mouth once daily in the morning for 4 weeks	Drug: Placebo Placebo capsule to match navarixin to be taken by mouth once daily in the morning for 4 weeks. Drug: Rescue medication Participant choice of short-acting beta-2 agonist (salbutamol/albuterol), anticholinergic, or combination medication as needed for asthma symptoms

Detailed Description:

Effect of treatment with navarixin (MK-7123, SCH 527123) on sputum neutrophils and asthma symptoms

Eligibility

Ages Eligible for Study: 18 Years to 70 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- 18 to <=70 years of age, either sex, any race.
- Induced sputum neutrophil count >=40% of total white blood cells and <10 million/mL at Screening.
- Documented diagnosis of asthma (within past 5 years), determined by at least one of the following: >=12% and 200 mL improvement in Forced Expiratory Volume in 1 second (FEV1) post-bronchodilator, and/or airway hyperresponsiveness (eg, positive methacholine challenge <8 mg/mL).
- Nonsmoker or previous smoker with cumulative smoking history less than 20 pack-years (pack-year = 20 cigarettes smoked daily for 1 year). Previous smokers may not have smoked within 1 year prior to Screening.
- Must not have had an exacerbation of asthma for 4 weeks prior to Screening and must be on a stable medication regimen for asthma at least 4 weeks prior to Screening.
- Must be receiving >=800 mcg/day of beclomethasone dipropionate (BDP) or equivalent for at least 3 months prior to Screening (and on stable dose for at least 4 weeks prior to Screening).
- Must be willing to give written informed consent to participate in the study
- Must be capable of complying with the dosing regimen, adhere to the visit schedule, and participate in all treatment procedures, including sputum induction.
- Female subject of childbearing potential must have a negative serum pregnancy test at Screening and must be using a medically acceptable, highly effective, adequate form of birth control (ie, failure rate <1% per year when used consistently and correctly) prior to Screening and agree to continue using it while in the study (Screening and Treatment Periods). Medically acceptable, highly effective forms of birth control are hormonal implants, oral contraceptives, medically acceptable prescribed intrauterine devices (IUDs), and monogamous relationship with a male partner who has had a vasectomy. Female subject who is not of childbearing potential must have a medical record of being surgically sterile (eg, hysterectomy, tubal ligation), or be at least 1 year postmenopausal. Absence of menses for at least 1 year will indicate that a female is postmenopausal. A female subject should be encouraged to continue using a highly effective method of birth control for 30 days following the end of treatment.
- Male subject must agree to use an adequate form of contraception for the duration of the study and agree to have sexual relations only with women who use a highly effective birth control method.

Exclusion Criteria:

- Chronic Obstructive Pulmonary Disease (COPD)/other relevant lung disease (other than asthma).
- 4 weeks prior to/or Screening: upper/lower respiratory tract infection.
- Prohibited medications received more recently than indicated washout prior to Screening
- Screening: Inadequate amount or difficulty producing sputum.
- Screening: Sputum neutrophil count over 10 million/mL.
- Screening: peripheral blood neutrophil (PBN) count <3000/µL.

- Post-bronchodilator FEV1 <1L.
- Clinically significant chronic infectious disease(s) (eg, Human Immunodeficiency Virus [HIV], hepatitis B or C).
- Allergy/sensitivity to study drug/excipients.
- Breast-feeding, pregnant/intends to become pregnant during study.
- Requiring mechanical ventilation for respiratory event within 6 months of Screening.
- Medical condition(s) (eg, hematologic, cardiovascular, renal, hepatic, neurologic, or metabolic) or medication that may interfere with effect of study medication.
- Within 30 days of Screening: any other investigational drug.
- Participation in any other clinical study.
- Part of the staff personnel involved with the study.
- Family member of investigational study staff.

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: NCT00632502

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Director Merck Sharp & Dohme Corp.

More Information

Publications:

Nair P, Gaga M, Zervas E, Alagha K, Hargreave FE, O'Byrne PM, Stryszak P, Gann L, Sadeh J, Chanez P; Study Investigators. Safety and efficacy of a CXCR2 antagonist in patients with severe asthma and sputum neutrophils: a randomized, placebo-controlled clinical trial. Clin Exp Allergy. 2012 Jul;42(7):1097-103. doi: 10.1111/j.1365-2222.2012.04014.x.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00632502 History of Changes
Other Study ID Numbers:	P05365 2007-005615-26 P05365
Study First Received:	February 29, 2008
Results First Received:	October 14, 2014
Last Updated:	October 28, 2015
Health Authority:	Greece: National Drug Authority

Additional relevant MeSH terms:

Asthma	Lung Diseases
Bronchial Diseases	Lung Diseases, Obstructive
Hypersensitivity	Respiratory Hypersensitivity
Hypersensitivity, Immediate	Respiratory Tract Diseases
Immune System Diseases	

ClinicalTrials.gov processed this record on May 08, 2016

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History of Changes

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

Results First Received: October 14, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Neutrophilic Asthma
Interventions:	Drug: Navarixin Drug: Placebo Drug: Rescue medication

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
Participants were considered to complete the study if they completed the follow-up visit, whether or not they completed treatment.

Reporting Groups

	Description
Navarixin	Navarixin 30 mg capsule to be taken by mouth once daily for 4 weeks
Placebo	Placebo capsule to be taken by mouth once daily for 4 weeks

Participant Flow: Overall Study

	Navarixin	Placebo
STARTED	**25**	**12**
Treated	**22**	**12**
Completed Treatment	**19**	**9**
COMPLETED	**22**	**11**
NOT COMPLETED	**3**	**1**
Adverse Event	**0**	**1**
Randomized not treated	**3**	**0**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All randomized participants who received study drug

Reporting Groups

	Description
Navarixin	Navarixin 30 mg capsule to be taken by mouth once daily for 4 weeks
Placebo	Placebo capsule to be taken by mouth once daily for 4 weeks
Total	Total of all reporting groups

Baseline Measures

	Navarixin	Placebo	Total
Number of Participants [units: participants]	**22**	**12**	**34**
Age [units: Years] Mean (Standard Deviation)	**48.7 (10.6)**	**53.9 (6.8)**	**50.6 (9.6)**
Gender [units: Participants]			
Female	**13**	**7**	**20**
Male	**9**	**5**	**14**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants Who Maintained an Absolute Peripheral Blood Neutrophil Count >=1500/µL [Time Frame: Up to 4 weeks]

Measure Type	Primary
Measure Title	Number of Participants Who Maintained an Absolute Peripheral Blood Neutrophil Count >=1500/µL
Measure Description	Peripheral blood neutrophil counts were performed on Day 2 and Weeks 1, 2, 3, and 4 of the treatment period
Time Frame	Up to 4 weeks
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.
The analysis population included all participants who received at least one dose of study drug

Reporting Groups

	Description
Navarixin	Navarixin 30 mg capsule to be taken by mouth once daily for 4 weeks
Placebo	Placebo capsule to be taken by mouth once daily for 4 weeks

Measured Values

	Navarixin	**Placebo**
Number of Participants Analyzed [units: participants]	**22**	**12**
Number of Participants Who Maintained an Absolute Peripheral Blood Neutrophil Count >=1500/µL [units: Number of participants]	**20**	**12**

No statistical analysis provided for Number of Participants Who Maintained an Absolute Peripheral Blood Neutrophil Count >=1500/µL

2. Secondary: Mean Change From Baseline in Sputum Absolute Neutrophil Count [Time Frame: Baseline and while on study drug (up to 4 weeks)]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Sputum Absolute Neutrophil Count
Measure Description	Induced sputum samples were obtained at Baseline and at Weeks 2 and 4 of the treatment period. Samples were collected before study drug administration using the nebulizer method and sent to a central laboratory for analysis. An average was taken over all post-baseline samples collected no later than one day after the last dose of study drug.
Time Frame	Baseline and while on study drug (up to 4 weeks)

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The analysis population included all randomized participants who received at least one dose of study drug and had sputum absolute neutrophil counts at Baseline or Week 4

Reporting Groups

	Description
Navarixin	Navarixin 30 mg capsule to be taken by mouth once daily for 4 weeks
Placebo	Placebo capsule to be taken by mouth once daily for 4 weeks

Measured Values

	Navarixin	**Placebo**
Number of Participants Analyzed [units: participants]	**18**	**11**
Mean Change From Baseline in Sputum Absolute Neutrophil Count **[units: Neutrophil count X10^9/L]** **Mean (Standard Deviation)**		
Baseline sputum absolute neutrophil count	**3.275 (3.995)**	**3.408 (2.973)**
Change from baseline at up to 4 weeks	**-0.270 (6.673)**	**0.680 (2.249)**

No statistical analysis provided for Mean Change From Baseline in Sputum Absolute Neutrophil Count

3. Secondary: Mean Change From Baseline in Total Asthma Symptom Score [Time Frame: Baseline and Weeks 1, 2, 3, and 4]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Total Asthma Symptom Score
Measure Description	Total Asthma Symptom Score is the sum of individual symptoms of wheezing, coughing, and dyspnea assessed twice daily (morning and evening) and is recorded on a comment diary card. Each of the symptoms receives a daily score from 0 (none) to 3 (severe), averaged over the two daily assessments. The total score ranges from 0 to 9, with a lower score indicating less severe asthma symptoms.
Time Frame	Baseline and Weeks 1, 2, 3, and 4
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 analysis population included all randomized participants who received at least one dose of study drug and had Asthma Symptom Scores evaluated at the time points reported

Reporting Groups

	Description
Navarixin	Navarixin (SCH 537123) 30 mg capsule to be taken by mouth once daily for 4 weeks
Placebo	Placebo capsule to be taken by mouth once daily for 4 weeks

Measured Values

	Navarixin	Placebo
Number of Participants Analyzed [units: participants]	**21**	**12**
Mean Change From Baseline in Total Asthma Symptom Score [units: Score on a scale] Mean (Standard Deviation)		
Baseline Total Asthma Symptom Score (n=21, 12)	**2.47 (1.83)**	**2.40 (1.30)**
Change at 1 week (n=21, 12)	**-0.07 (1.01)**	**0.05 (0.78)**
Change at 2 weeks (n=20, 12)	**-0.25 (1.50)**	**0.19 (1.14)**
Change at 3 weeks (n=19, 12)	**-0.19 (1.56)**	**0.04 (1.30)**
Change at 4 weeks (n=18, 9)	**-0.00 (1.62)**	**-0.26 (2.06)**

No statistical analysis provided for Mean Change From Baseline in Total Asthma Symptom Score

4. Secondary: Change From Baseline in Post-Bronchodilator Forced Expiratory Volume in One Second (FEV1) [Time Frame: Baseline and up to 4 weeks]

Measure Type	Secondary
Measure Title	Change From Baseline in Post-Bronchodilator Forced Expiratory Volume in One Second (FEV1)
Measure Description	Spirometry was used to measure post-bronchodilator FEV1 at Baseline and before study drug administration at Weeks 1, 2, 3, and 4. Participants received 4 puffs of bronchodilator (salbutamol hydrofluoroalkane or equivalent) at 30-second intervals and spirometry was performed 30 minutes later. The mean change from baseline is based on the average change over all post-baseline assessments.
Time Frame	Baseline and up to 4 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The analysis population included all randomized participants who received at least one dose of study drug and had endpoint assessment at Baseline or at any post-baseline visit

Reporting Groups

	Description
Navarixin	Navarixin (SCH 537123) 30 mg capsule to be taken by mouth once daily for 4

	weeks
Placebo	Placebo capsule to be taken by mouth once daily for 4 weeks

Measured Values

	Navarixin	Placebo
Number of Participants Analyzed [units: participants]	**22**	**12**
Change From Baseline in Post-Bronchodilator Forced Expiratory Volume in One Second (FEV1) [units: Liters] Mean (Standard Deviation)		
Baseline FEV1	**2.197 (0.948)**	**1.851 (0.469)**
Average change from baseline at up to 4 weeks	**-0.099 (0.315)**	**-0.094 (0.106)**

No statistical analysis provided for Change From Baseline in Post-Bronchodilator Forced Expiratory Volume in One Second (FEV1)

5. Secondary: Change From Baseline in Asthma Quality of Life Questionnaire With Standardized Activities (AQLQ[S]) [Time Frame: Baseline and up to 4 weeks]

Measure Type	Secondary
Measure Title	Change From Baseline in Asthma Quality of Life Questionnaire With Standardized Activities (AQLQ[S])
Measure Description	The AQLQ[S] was administered at Baseline and at Weeks 2 and 4. The assessment consists of a 32-item questionnaire covering 4 domains: symptoms, emotional functioning, impact of environmental stimuli, and activity limitation. Each item receives a score from 1 (worst, or most affected) to 7 (not at all affected). The score is the mean across all items, and ranges from 1 to 7. The mean change from baseline is based on the average change over all post-baseline assessments.
Time Frame	Baseline and up to 4 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The analysis population included all randomized participants who received at least one dose of study drug and had endpoint evaluation at Baseline or at any post-baseline visit

Reporting Groups

	Description
Navarixin	Navarixin 30 mg capsule to be taken by mouth once daily for 4 weeks
Placebo	Placebo capsule to be taken by mouth once daily for 4 weeks

Measured Values

	Navarixin	Placebo
Number of Participants Analyzed [units: participants]	**21**	**12**

Change From Baseline in Asthma Quality of Life Questionnaire With Standardized Activities (AQLQ[S]) **[units: Score on a scale]** **Mean (Standard Deviation)**		
Baseline AQLQ[S] Score	**4.822 (1.568)**	**4.897 (1.128)**
Average change from baseline at up to 4 weeks	**0.165 (0.901)**	**0.119 (0.936)**

No statistical analysis provided for Change From Baseline in Asthma Quality of Life Questionnaire With Standardized Activities (AQLQ[S])

6. Secondary: Number of Participants With an Adverse Event (AE) [Time Frame: Up to 5 weeks]

Measure Type	Secondary
Measure Title	Number of Participants With an Adverse Event (AE)
Measure Description	An AE is any untoward medical occurrence in a participant administered study drug which does not necessarily have a causal relationship with the treatment. AEs may include the onset of new illness and the exacerbation of pre-existing conditions.
Time Frame	Up to 5 weeks
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.
The analysis population included all participants who received at least one dose of study drug

Reporting Groups

	Description
Navarixin	Navarixin 30 mg capsule to be taken by mouth once daily for 4 weeks
Placebo	Placebo capsule to be taken by mouth once daily for 4 weeks

Measured Values

	Navarixin	**Placebo**
Number of Participants Analyzed **[units: participants]**	**22**	**12**
Number of Participants With an Adverse Event (AE) **[units: Participants]**	**13**	**8**

No statistical analysis provided for Number of Participants With an Adverse Event (AE)

7. Secondary: Number of Participants With an Electrocardiogram Adverse Event [Time Frame: Week 4]

Measure Type	Secondary

Measure Title	Number of Participants With an Electrocardiogram Adverse Event
Measure Description	The endpoint measured was any electrocardiogram abnormality that was reported as an AE. An AE is any untoward medical occurrence in a participant administered study drug which does not necessarily have a causal relationship with the treatment. AEs may include the onset of new illness and the exacerbation of pre-existing conditions.
Time Frame	Week 4
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.
The analysis population included all participants who received at least one dose of study drug

Reporting Groups

	Description
Navarixin	Navarixin 30 mg capsule to be taken by mouth once daily for 4 weeks
Placebo	Placebo capsule to be taken by mouth once daily for 4 weeks

Measured Values

	Navarixin	**Placebo**
Number of Participants Analyzed [units: participants]	**22**	**12**
Number of Participants With an Electrocardiogram Adverse Event [units: Participants]	**0**	**0**

No statistical analysis provided for Number of Participants With an Electrocardiogram Adverse Event

8. Secondary: Number of Participants With a Laboratory Adverse Event [Time Frame: Up to 5 weeks]

Measure Type	Secondary
Measure Title	Number of Participants With a Laboratory Adverse Event
Measure Description	The endpoint measured was any laboratory (hematology, blood chemistry, or urinalysis) abnormality that was reported as an AE. An AE is any untoward medical occurrence in a participant administered study drug which does not necessarily have a causal relationship with the treatment. AEs may include the onset of new illness and the exacerbation of pre-existing conditions.
Time Frame	Up to 5 weeks
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.
The analysis population included all participants who received at least one dose of study drug

Reporting Groups

	Description
Navarixin	Navarixin 30 mg capsule to be taken by mouth once daily for 4 weeks
Placebo	Placebo capsule to be taken by mouth once daily for 4 weeks

Measured Values

	Navarixin	Placebo
Number of Participants Analyzed [units: participants]	**22**	**12**
Number of Participants With a Laboratory Adverse Event [units: Participants]	**2**	**0**

No statistical analysis provided for Number of Participants With a Laboratory Adverse Event

9. Secondary: Number of Participants Who Discontinued the Study Because of an Adverse Event [Time Frame: Up to 5 weeks]

Measure Type	Secondary
Measure Title	Number of Participants Who Discontinued the Study Because of an Adverse Event
Measure Description	An AE is any untoward medical occurrence in a participant administered study drug which does not necessarily have a causal relationship with the treatment. AEs may include the onset of new illness and the exacerbation of pre-existing conditions.
Time Frame	Up to 5 weeks
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.
The analysis population included all participants who received at least one dose of study drug

Reporting Groups

	Description
Navarixin	Navarixin 30 mg capsule to be taken by mouth once daily for 4 weeks
Placebo	Placebo capsule to be taken by mouth once daily for 4 weeks

Measured Values

	Navarixin	Placebo
Number of Participants Analyzed [units: participants]	**22**	**12**
Number of Participants Who Discontinued the Study Because of an Adverse Event [units: Participants]	**0**	**1**

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

10. Secondary: Number of Participants Who Discontinued Treatment Because of an Adverse Event or a Protocol-defined Clinical Event [Time Frame: Up to 4 weeks]

Measure Type	Secondary
Measure Title	Number of Participants Who Discontinued Treatment Because of an Adverse Event or a Protocol-defined Clinical Event
Measure Description	An AE is any untoward medical occurrence in a participant administered study drug which does not necessarily have a causal relationship with the treatment. AEs may include the onset of new illness and the exacerbation of pre-existing conditions. A protocol-defined clinical event is an asthma exacerbation requiring addition of or increase in systemic steroids, as determined by the investigator.
Time Frame	Up to 4 weeks
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.
The analysis population included all participants who received at least one dose of study drug

Reporting Groups

	Description
Navarixin	Navarixin 30 mg capsule to be taken by mouth once daily for 4 weeks
Placebo	Placebo capsule to be taken by mouth once daily for 4 weeks

Measured Values

	Navarixin	**Placebo**
Number of Participants Analyzed [units: participants]	**22**	**12**
Number of Participants Who Discontinued Treatment Because of an Adverse Event or a Protocol-defined Clinical Event [units: Participants]		
Adverse event	**2**	**2**
Protocol-defined clinical event	**1**	**1**

No statistical analysis provided for Number of Participants Who Discontinued Treatment Because of an Adverse Event or a Protocol-defined Clinical Event

11. Secondary: Maximum Plasma Concentration of Navarixin (Cmax) [Time Frame: Week 1, 2, 3, and 4]

Measure Type	Secondary
Measure Title	Maximum Plasma Concentration of Navarixin (Cmax)

Measure Description	Plasma samples were to be collected at baseline and up to 24 hours after dosing with navarixin at Weeks 1, 2, 3, and 4
Time Frame	Week 1, 2, 3, and 4
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 analysis population was to include all participants who received at least one dose of navarixin and had navarixin plasma concentrations available for endpoint evaluation. The planned outcome measure was not evaluated.

Reporting Groups

	Description
Navarixin	Navarixin 30 mg capsule to be taken by mouth once daily for 4 weeks

Measured Values

	Navarixin
Number of Participants Analyzed [units: participants]	**0**
Maximum Plasma Concentration of Navarixin (Cmax)	

No statistical analysis provided for Maximum Plasma Concentration of Navarixin (Cmax)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 5 weeks
Additional Description	No text entered.

Reporting Groups

	Description
Navarixin	Navarixin 30 mg capsule to be taken by mouth once daily for 4 weeks
Placebo	Placebo capsule to be taken by mouth once daily for 4 weeks

Serious Adverse Events

	Navarixin	**Placebo**
Total, serious adverse events		
# participants affected / at risk	**0/22 (0.00%)**	**0/12 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 5 weeks
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Navarixin	Navarixin 30 mg capsule to be taken by mouth once daily for 4 weeks
Placebo	Placebo capsule to be taken by mouth once daily for 4 weeks

Other Adverse Events

	Navarixin	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	**11/22 (50.00%)**	**8/12 (66.67%)**
Eye disorders		
Conjunctivitis † 1		
# participants affected / at risk	**0/22 (0.00%)**	**1/12 (8.33%)**
# events	**0**	**1**
Gastrointestinal disorders		
Abdominal pain upper † 1		
# participants affected / at risk	**2/22 (9.09%)**	**0/12 (0.00%)**
# events	**2**	**0**
Diarrhoea † 1		
# participants affected / at risk	**0/22 (0.00%)**	**1/12 (8.33%)**
# events	**0**	**2**
Nausea † 1		
# participants affected / at risk	**2/22 (9.09%)**	**0/12 (0.00%)**
# events	**2**	**0**
Infections and infestations		
Bacterial infection † 1		
# participants affected / at risk	**0/22 (0.00%)**	**1/12 (8.33%)**
# events	**0**	**1**
Furuncle † 1		
# participants affected / at risk	**0/22 (0.00%)**	**1/12 (8.33%)**
# events	**0**	**1**

Influenza † 1		
# participants affected / at risk	**2/22 (9.09%)**	**0/12 (0.00%)**
# events	**2**	**0**
Lower respiratory tract infection † 1		
# participants affected / at risk	**0/22 (0.00%)**	**1/12 (8.33%)**
# events	**0**	**1**
Nasopharyngitis † 1		
# participants affected / at risk	**4/22 (18.18%)**	**1/12 (8.33%)**
# events	**4**	**1**
Upper respiratory tract infection † 1		
# participants affected / at risk	**1/22 (4.55%)**	**1/12 (8.33%)**
# events	**1**	**1**
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	**0/22 (0.00%)**	**1/12 (8.33%)**
# events	**0**	**1**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**3/22 (13.64%)**	**4/12 (33.33%)**
# events	**3**	**7**
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	**0/22 (0.00%)**	**1/12 (8.33%)**
# events	**0**	**1**
Dysphonia † 1		
# participants affected / at risk	**0/22 (0.00%)**	**1/12 (8.33%)**
# events	**0**	**1**
Oropharyngeal pain † 1		
# participants affected / at risk	**2/22 (9.09%)**	**0/12 (0.00%)**
# events	**2**	**0**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 11.1

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 investigator agrees to provide to the sponsor 45 days prior to submission for publication or presentation, review copies of abstracts or manuscripts for publication that report any results of the study. The sponsor shall have the right to review and comment with respect to publications, abstracts, slides, and manuscripts and the right to review and comment on the data analysis and presentation.

Results Point of Contact:

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

Publications of Results:

Nair P, Gaga M, Zervas E, Alagha K, Hargreave FE, O'Byrne PM, Stryszak P, Gann L, Sadeh J, Chanez P; Study Investigators. Safety and efficacy of a CXCR2 antagonist in patients with severe asthma and sputum neutrophils: a randomized, placebo-controlled clinical trial. Clin Exp Allergy. 2012 Jul;42(7):1097-103. doi: 10.1111/j.1365-2222.2012.04014.x.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00632502 History of Changes
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Last Updated:	October 28, 2015
Health Authority:	Greece: National Drug Authority

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