A Study to Assess the Clinical Effects of Navarixin in Participants With Psoriasis (MK-7123-009)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00684593

First received: May 22, 2008
Last updated: September 21, 2015
Last verified: September 2015
History of Changes

Purpose

This study was conducted: 1) to assess the clinical effect of Navarixin on the Psoriasis Activity and Severity Index (PASI), 2) to determine the effects of Navarixin on the Physician's Global Assessment (PGA), 3) to evaluate the safety and tolerability of Navarixin, and 4) to determine the multiple-dose pharmacokinetics of Navarixin.

Condition	Intervention	Phase
Psoriasis	Drug: Navarixin 10 mg Other: Placebo	Phase 2

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

Official Title: A Study to Assess the Clinical Effects of SCH 527123 in Psoriasis

Resource links provided by NLM:

MedlinePlus related topics: Psoriasis

U.S. FDA Resources

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

Primary Outcome Measures:

- Mean Percent Change From Baseline in the Psoriasis and Activity Severity Index (PASI) Score at Day 29 [Time Frame: Baseline and Day 29] [Designated as safety issue: No]

PASI score is a means to qualify the extent and severity of psoriatic lesions. The total score is calculated as the sum of the extent and severity of lesions on the head, arms, trunk, and legs and the score can range from 0 (no symptoms) to 72 (maximum symptoms).

Secondary Outcome Measures:

- Number of Participants by Physician's Assessment of Global Improvement (PGA) Score At Day 29 [Time Frame: Day 29] [Designated as safety issue: No]

  The PGA is a questionnaire that asks the treating physician to rate the participant's signs and symptoms on a scale where 0=worse, 1=unchanged, 2= slight improvement, 3= fair improvement, 4= good improvement, 5= excellent improvement, and 6=cleared, with higher scores indicating better outcomes.

- Mean Maximum Plasma Concentration (Cmax) of Navarixin at Day 28 [Time Frame: Day 28] [Designated as safety issue: No]

  Participant blood samples were collected at 0, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12, and 24 hours following oral administration of Navarixin to determine the mean Cmax at Day 28. Blood samples were not collected from the placebo group to evaluate this endpoint.

- Mean Area Under the Plasma Concentration-Time Curve From Time 0-24 Hours (AUC [0-24]) of Navarixin at Day 28 [Time Frame: Day 28] [Designated as safety issue: No]

  Participant blood samples were collected at 0, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12, and 24 hours following oral administration of Navarixin to determine the mean AUC(0-24) at Day 28. Blood samples were not collected from the placebo group to evaluate this endpoint.

- Mean Terminal Phase Half-life (T1/2) of Navarixin at Day 28 [Time Frame: Day 28] [Designated as safety issue: No]

  Participant blood samples were collected at 0, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12, and 24 hours to determine the mean T1/2 of Navarixin following oral administration at Day 28. Blood samples were not collected from the placebo group to evaluate this endpoint.

- Median Time to Maximum Plasma Concentration (Tmax) of Navarixin at Day 28 [Time Frame: Day 28] [Designated as safety issue: No]

  Participant blood samples were collected at 0, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12, and 24 hours following oral administration of Navarixin to determine the Mean Tmax at Day 28. Blood samples were not collected from the placebo group to evaluate this endpoint.

Enrollment:	31
Study Start Date:	June 2007
Study Completion Date:	October 2007
Primary Completion Date:	October 2007 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Navarixin Navarixin 30 mg administered orally once daily for 28 days.	Drug: Navarixin 10 mg Navarixin capsules orally, once daily for 28 days.
Placebo Comparator: Placebo Matching placebo to Navarixin administered orally once daily for 28 days.	Other: Placebo Matching placebo capsules to Navarixin orally, once daily for 28 days.

Eligibility

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

Criteria

Inclusion Criteria:

- Body Mass Index (BMI) 19 to 34, BMI = weight (kg)/height (m^2).
- Must have a diagnosis of psoriasis vulgaris (PASI >8) present for at least 1 year. Participants with an on-therapy PASI <=8 at Screening may be considered for inclusion. Participants must be discussed with the Sponsor prior to enrollment and the subject must have indicated that they are not satisfied with current therapy. To be included, participants must have a PASI >8 following washout of their current psoriasis therapy.

Target lesion selected must be located on the head, trunk, arms or legs and be at least 10 cm^2 in size. The lesion's total numerical ratings for erythema, infiltration, and desquamation must be at least 6 out of the possible 12. Severity score for desquamation must be at least 2.

- Vital sign measurements (taken after ~3 minutes in a supine position) must be within the following ranges: oral body temperature between 35.0°C to 37.5°C; systolic blood pressure, 90 to 160 mm Hg; diastolic blood pressure, 45 to 90 mm Hg; pulse rate, 40 to 100 bpm.
- Have stable disease (ie, off treatment PASI during Screening period and Baseline PASI should not differ by more than 40%).
- Clinical laboratory tests (CBC, blood chemistries, and urinalysis) must be within normal limits or clinically acceptable to the investigator/sponsor. Participants must have a neutrophil count of at least 2 x 10^9/L to be included.
- Free of any clinically significant disease (other than psoriasis).
- Willing to give written informed consent and able to adhere to dose and visit schedules.
- For female participants: Negative serum pregnancy test (beta-hCG) and urine pregnancy test. Agree to use medically accepted methods of contraception during and for an appropriate pre-study period while receiving protocol specified medication, and for 1 month after stopping medication. Female participants of non-childbearing potential must be surgically sterilized or be postmenopausal.
- Male subject must agree to use an adequate form of contraception for the duration of the study.
- At Screening, ECG conduction intervals must be within gender specific normal range (ie, QTc for males <430 msec and females <450 msec) or if not within the normal range, the values must be considered clinically insignificant by the investigator and sponsor.

Exclusion Criteria:

- Female participants who are pregnant, intend to become pregnant (within 3 months of ending the study), or are breastfeeding.
- Participants who, in the opinion of the investigator, will not be able to participate optimally in the study.
- Any surgical or medical condition which might significantly alter the absorption, distribution, metabolism or excretion of any drug.
- History of any infectious disease within 4 weeks prior to drug administration and/or are positive for hepatitis B surface antigen, hepatitis C antibodies or human immunodeficiency virus (HIV).
- Immunocompromised participants.
- Positive screen for drugs with a high potential for abuse or have a history of drug or alcohol abuse in the past 2 years.
- History of mental instability or who have been treated for mood disorders.
- Donated blood in the past 60 days.
- Previous treatment with study medication.
- Currently participating in another clinical study or have participated in a clinical study within 30 days.
- Part of the study staff personnel or family members of the study staff personnel.
- Demonstrated clinically significant (requiring intervention) allergic reactions or who are known to be allergic to components of local anesthetics.

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: NCT00684593

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Director Merck Sharp & Dohme Corp.

More Information

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00684593 History of Changes
Other Study ID Numbers:	P04481 2006-006601-83 P04481
Study First Received:	May 22, 2008
Results First Received:	September 26, 2014
Last Updated:	September 21, 2015
Health Authority:	Denmark: Danish Medicines Agency

Additional relevant MeSH terms:
Psoriasis
Skin Diseases
Skin Diseases, Papulosquamous

ClinicalTrials.gov processed this record on May 08, 2016

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First received: May 22, 2008
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Last verified: September 2015
History of Changes

Results First Received: September 26, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Psoriasis
Interventions:	Drug: Navarixin 10 mg Other: 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
Navarixin	Navarixin 30 mg administered orally once daily for 28 days.
Placebo	Matching placebo to Navarixin administered orally once daily for 28 days.

Participant Flow: Overall Study

	Navarixin	Placebo
STARTED	**21**	**10**
COMPLETED	**21**	**8**
NOT COMPLETED	**0**	**2**
Adverse Event	**0**	**2**

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
Navarixin	Navarixin 30 mg administered orally once daily for 28 days.
Placebo	Matching placebo to Navarixin administered orally once daily for 28 days.
Total	Total of all reporting groups

Baseline Measures

	Navarixin	Placebo	Total
Number of Participants [units: participants]	**21**	**10**	**31**
Age [units: Years] Mean (Standard Deviation)	**49.5 (10.5)**	**43.9 (13.4)**	**47.7 (11.6)**
Gender [units: Participants]			
Female	**2**	**2**	**4**
Male	**19**	**8**	**27**

Outcome Measures

Hide All Outcome Measures

1. Primary: Mean Percent Change From Baseline in the Psoriasis and Activity Severity Index (PASI) Score at Day 29 [Time Frame: Baseline and Day 29]

Measure Type	Primary
Measure Title	Mean Percent Change From Baseline in the Psoriasis and Activity Severity Index (PASI) Score at Day 29
Measure Description	PASI score is a means to qualify the extent and severity of psoriatic lesions. The total score is calculated as the sum of the extent and severity of lesions on the head, arms, trunk, and legs and the score can range from 0 (no symptoms) to 72 (maximum symptoms).
Time Frame	Baseline and Day 29
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 population consisted of all treated participants with follow-up.

Reporting Groups

	Description
Navarixin	Navarixin 30 mg administered orally once daily for 28 days.
Placebo	Matching placebo to SCH 527123 administered orally once daily for 28 days.

Measured Values

	Navarixin	**Placebo**
Number of Participants Analyzed [units: participants]	**21**	**9**
Mean Percent Change From Baseline in the Psoriasis and Activity Severity Index (PASI) Score at Day 29 [units: Score on a Scale] Mean (Standard Deviation)	**-3.30 (15.05)**	**-2.14 (13.26)**

No statistical analysis provided for Mean Percent Change From Baseline in the Psoriasis and Activity Severity Index (PASI) Score at Day 29

2. Secondary: Number of Participants by Physician's Assessment of Global Improvement (PGA) Score At Day 29 [Time Frame: Day 29]

Measure Type	Secondary
Measure Title	Number of Participants by Physician's Assessment of Global Improvement (PGA) Score At Day 29
Measure Description	The PGA is a questionnaire that asks the treating physician to rate the participant's signs and symptoms on a scale where 0=worse, 1=unchanged, 2= slight improvement, 3= fair improvement, 4= good improvement, 5= excellent improvement, and 6=cleared, with higher scores indicating better outcomes.
Time Frame	Day 29
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 population consisted of all treated participants with follow-up.

Reporting Groups

	Description
Navarixin	Navarixin 30 mg administered orally once daily for 28 days.
Placebo	Matching placebo to SCH 527123 administered orally once daily for 28 days.

Measured Values

	Navarixin	Placebo
Number of Participants Analyzed [units: participants]	**21**	**9**
Number of Participants by Physician's Assessment of Global Improvement (PGA) Score At Day 29 [units: Participants]		
Score = 0 (worse)	**7**	**2**
Score = 1 (unchanged)	**6**	**2**
Score = 2 (slight improvement)	**8**	**4**
Score = 3 (fair improvement)	**0**	**1**
Score = 4 (good improvement)	**0**	**0**
Score = 5 (excellent improvement)	**0**	**0**
Score = 6 (cleared)	**0**	**0**

No statistical analysis provided for Number of Participants by Physician's Assessment of Global Improvement (PGA) Score At Day 29

3. Secondary: Mean Maximum Plasma Concentration (Cmax) of Navarixin at Day 28 [Time Frame: Day 28]

Measure Type	Secondary
Measure Title	Mean Maximum Plasma Concentration (Cmax) of Navarixin at Day 28
Measure Description	Participant blood samples were collected at 0, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12, and 24 hours following oral administration of Navarixin to determine the mean Cmax at Day 28. Blood samples were not collected from the placebo group to evaluate this endpoint.
Time Frame	Day 28
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 population consisted of all participants for which serum samples were available for the determination of Cmax at Day 28. One participant was excluded due to erroneous blood sample collection relative to Navarixin dosing.

Reporting Groups

	Description
Navarixin	Navarixin 30 mg administered orally once daily for 28 days.

Measured Values

	Navarixin
Number of Participants Analyzed [units: participants]	**20**
Mean Maximum Plasma Concentration (Cmax) of Navarixin at Day 28 [units: ng/mL] Mean (Standard Deviation)	**209.85 (51.50)**

No statistical analysis provided for Mean Maximum Plasma Concentration (Cmax) of Navarixin at Day 28

4. Secondary: Mean Area Under the Plasma Concentration-Time Curve From Time 0-24 Hours (AUC [0-24]) of Navarixin at Day 28 [Time Frame: Day 28]

Measure Type	Secondary
Measure Title	Mean Area Under the Plasma Concentration-Time Curve From Time 0-24 Hours (AUC [0-24]) of Navarixin at Day 28
Measure Description	Participant blood samples were collected at 0, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12, and 24 hours following oral administration of Navarixin to determine the mean AUC(0-24) at Day 28. Blood samples were not collected from the placebo group to evaluate this endpoint.
Time Frame	Day 28
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 population consisted of all enrolled participants for which serum samples were evaluable at Day 28 for AUC (0-24). One participant was excluded due to erroneous blood sample collection relative to Navarixin dosing.

Reporting Groups

	Description
Navarixin	Navarixin 30 mg administered orally once daily for 28 days.

Measured Values

	Navarixin
Number of Participants Analyzed [units: participants]	**20**
Mean Area Under the Plasma Concentration-Time Curve From Time 0-24 Hours (AUC [0-24]) of Navarixin at Day 28 [units: hr*ng/mL] Mean (Standard Deviation)	**420.37 (67.57)**

No statistical analysis provided for Mean Area Under the Plasma Concentration-Time Curve From Time 0-24 Hours (AUC [0-24]) of Navarixin at Day

28

5. Secondary: Mean Terminal Phase Half-life (T1/2) of Navarixin at Day 28 [Time Frame: Day 28]

Measure Type	Secondary
Measure Title	Mean Terminal Phase Half-life (T1/2) of Navarixin at Day 28
Measure Description	Participant blood samples were collected at 0, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12, and 24 hours to determine the mean T1/2 of Navarixin following oral administration at Day 28. Blood samples were not collected from the placebo group to evaluate this endpoint.
Time Frame	Day 28
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 population consisted of all enrolled participants for which serum samples were evaluable for T1/2. One participant was excluded due to erroneous blood sample collection relative to Navarixin dosing. An additional 2 participants were excluded from the population because their T1/2 was incalculable.

Reporting Groups

	Description
Navarixin	Navarixin 30 mg administered orally once daily for 28 days.

Measured Values

	Navarixin
Number of Participants Analyzed [units: participants]	**18**
Mean Terminal Phase Half-life (T1/2) of Navarixin at Day 28 [units: Hours] Mean (Standard Deviation)	**13.02 (6.63)**

No statistical analysis provided for Mean Terminal Phase Half-life (T1/2) of Navarixin at Day 28

6. Secondary: Median Time to Maximum Plasma Concentration (Tmax) of Navarixin at Day 28 [Time Frame: Day 28]

Measure Type	Secondary
Measure Title	Median Time to Maximum Plasma Concentration (Tmax) of Navarixin at Day 28
Measure Description	Participant blood samples were collected at 0, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12, and 24 hours following oral administration of Navarixin to determine the Mean Tmax at Day 28. Blood samples were not collected from the placebo group to evaluate this endpoint.
Time Frame	Day 28
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 population consisted of all participants for which serum samples were available for the determination of Tmax at Day 28.

Reporting Groups

	Description
Navarixin	Navarixin 30 mg administered orally once daily for 28 days.

Measured Values

	Navarixin
Number of Participants Analyzed [units: participants]	**21**
Median Time to Maximum Plasma Concentration (Tmax) of Navarixin at Day 28 [units: Hours] Median (Full Range)	**0.50 (0.50 to 1.00)**

No statistical analysis provided for Median Time to Maximum Plasma Concentration (Tmax) of Navarixin at Day 28

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to Day 43
Additional Description	No text entered.

Reporting Groups

	Description
Navarixin	Navarixin 30 mg administered orally once daily for 28 days.
Placebo	Matching placebo to Navarixin administered orally once daily for 28 days.

Serious Adverse Events

	Navarixin	Placebo
Total, serious adverse events		
# participants affected / at risk	**0/21 (0.00%)**	**1/10 (10.00%)**
Vascular disorders		
Venous Thrombosis Limb † 1		
# participants affected / at risk	**0/21 (0.00%)**	**1/10 (10.00%)**
# events	**0**	**1**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to Day 43
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Navarixin	Navarixin 30 mg administered orally once daily for 28 days.
Placebo	Matching placebo to Navarixin administered orally once daily for 28 days.

Other Adverse Events

	Navarixin	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	**12/21 (57.14%)**	**5/10 (50.00%)**
Gastrointestinal disorders		
Diarrhoea † 1		
# participants affected / at risk	**1/21 (4.76%)**	**1/10 (10.00%)**
# events	**1**	**1**
General disorders		
Fatigue † 1		
# participants affected / at risk	**1/21 (4.76%)**	**1/10 (10.00%)**
# events	**1**	**1**
Infections and infestations		
Nasopharyngitis † 1		
# participants affected / at risk	**6/21 (28.57%)**	**0/10 (0.00%)**
# events	**6**	**0**
Metabolism and nutrition disorders		
Hyperglycaemia † 1		
# participants affected / at risk	**2/21 (9.52%)**	**0/10 (0.00%)**
# events	**2**	**0**
Musculoskeletal and connective tissue disorders		
Back Pain † 1		

# participants affected / at risk	**2/21 (9.52%)**	**0/10 (0.00%)**
# events	**2**	**0**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**5/21 (23.81%)**	**2/10 (20.00%)**
# events	**6**	**5**
Reproductive system and breast disorders		
Dysmenorrhoea † 1		
# participants affected / at risk	**0/21 (0.00%)**	**1/10 (10.00%)**
# events	**0**	**1**
Respiratory, thoracic and mediastinal disorders		
Pharyngolaryngeal Pain † 1		
# participants affected / at risk	**3/21 (14.29%)**	**0/10 (0.00%)**
# events	**3**	**0**

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

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** 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 with regard to (1) proprietary information that is protected, (2) the accuracy of the information contained in the publication, and (3) to ensure that the presentation is fairly balanced and in compliance with FDA regulations.

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:	NCT00684593 History of Changes
Other Study ID Numbers:	P04481 2006-006601-83 (EudraCT Number) P04481 (Other Identifier: Merck Protocol Number)</br>
Study First Received:	May 22, 2008
Results First Received:	September 26, 2014
Last Updated:	September 21, 2015
Health Authority:	Denmark: Danish Medicines Agency

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