The effects of SCH351125 on posriatic plaque immunohistochemistry, and chemokine expression in patients with moderate to severe psoriasis (protocol No.P03657) SCH351125.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21684

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Psoriasis.

Sponsors and support

Primary sponsor: Schering Plough Research Institute, Kenilworth, NJ.
Source(s) of monetary or material Support: Schering Plough Research Institute, Kenilworth, NJ.

Intervention

Outcome measures

Primary outcome

1. To determine the effects of SCH 351125, a CCR5 receptor antagonist, on psoriatic plaque cellularity;

2. To determine safety and tolerability of SCH 351125 in psoriatic patients.

Secondary outcome

1. Expression of chemokine mRNA within the psoriatic plaque and peripheral blood;

2. Peripheral blood chemokines and CCR5 expressing cells;

3. Psoriasis Area and Severity Index (PASI) and Physician Global assessment (PGA).

Study description

Background summary

Background:

Several reports have indicated that the chemokine receptor CCR5 and its ligands, escpecially CCL5 (formerly known as RANTES), may play a role in the pathogenesis of psoriasis. CCR5 targeted treatment could therefore be a therapeutic option for psoriasis patients.

Objectives:

Primary, to determine the effects of SCH351125, a CCR5 receptor antagonist, on psoriatic plaque cellularity and to determine safety and tolerability of SCH351125 in psoriatic patients. Secondary, to determine the effect of SCH351125 on expression of chemokine mRNA within the psoriatic plaque and peripheral blood, on peripheral blood chemokines and CCR5 expressing cells, and on PASI and PGA.

Study objective

Several reports have indicated that the chemokine receptor CCR5 and its ligands, escpecially CCL5 (formerly known as RANTES), may play a role in the pathogenesis of psoriasis. CCR5 targeted treatment could therefore be a therapeutic option for psoriasis patients.

Study design

N/A

Intervention

Subjects with moderate/severe chronic plaque sporiasis were enrolled in a randomized double-blind, placebo-controlled, parallel-group study exposed to either SCH 351125 50 mg BID or matched placebo, in a 2:1 ratio. for 28 days.

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Eligibility criteria

Inclusion criteria

1. Patients 18 to 75 years of age, of either sex, and of any race;

2. Patients must not be currently receiving treatment and have a diagnosis of moderate to severe psoriasis vulgaris (PASI > 8) which must be established and must have been present for at least one year;

3. The target lesion selected must be located on the trunk, arms or legs and be at least 10 cm2 in size;

4. The selected target lesion’s total numerical ratings for erythema, induration, and scaling must be at least 6 out of the possible 9 using the following definitions for each sign: 0=none, 1=mild, 2=moderate, 3= severe. The severity score for scaling must be at least 2;

5. Subjects’ clinical laboratory tests (CBC, blood chemistries, and urinalysis) must be within normal limits or clinically acceptable to the investigator/sponsor;

6. Subjects must be free of any clinically significant disease (other than psoriasis) that would interfere with the study evaluations and/or study safety;

7. Subjects must be willing to give written informed consent and able to adhere to dose and visit schedules;

8. Females must not be breastfeeding, and either be of nonchildbearing potential (ie, sterilized via hysterectomy or bilateral tubal ligation or at least 1 year postmenopausal) or if of child bearing potential, must be practicing effective contraceptive methods from at least 2 weeks prior to Day 1 and until 30 days following cessation of dosing;

9. Female subjects of childbearing potential must have a negative serum pregnancy test (beta-hCG) at Screening.

Exclusion criteria

1. Female subjects who are pregnant, intend to become pregnant, or are nursing;

2. Subjects who have taken methotrexate, cyclosporin or systemic retinoids with in 6 weeks of treatment or topical antipsoriasis therapy within two weeks of treatment. All other prescription medication must be discontinued for at least 28 days prior to treatment. No other drugs (except acetaminophen), including vitamins, herbal supplements, homeopathic or over the counter medications are allowed with 14 days of treatment administration;

3. Excluded treatments during the study. Subjects who must take any drug during the study period;

4. Subjects with any preexisting cardiovascular disease;

5. Individuals who have received any vaccinations within 30 days prior to Screening or a scheduled to receive a vaccination during the study;

6. Subjects who are positive for hepatitis B surface antigen, hepatitis C antibodies or for HIV antibodies;

7. Subjects who are in a situation or have any condition that, in the opinion of the investigator, may interfere with optimal participation in the study;

8. Subjects who have used any investigational drugs within 28 days of screening;

9. Subjects who are not willing to follow the study restrictions or procedures;

10. Individuals with any clinically significant history of food or drug allergy or allergy to any component of SCH 351125;

11. Subjects who are participating in any other clinical study;

12. Subjects who are part of the staff personnel directly involved with this study;

13. Subjects who are a family member of the investigational study staff.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2004
Enrollment:	32
Type:	Actual

Ethics review

Positive opinion

Date:	24-01-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL866
NTR-old	NTR880
Other	: N/A
ISRCTN	ISRCTN14986467

Study results

Summary results
1. Arch Dermatol Res. 2007 Sep;299(7):305-13. Epub 2007 Jul 24.
