

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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21684

Bron

Nationaal Trial Register

Verkorte titel

N/A

Aandoening

Psoriasis.

Ondersteuning

Primaire sponsor: Schering Plough Research Institute, Kenilworth, NJ.

Overige ondersteuning: Schering Plough Research Institute, Kenilworth, NJ.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Several reports have indicated that the chemokine receptor CCR5 and its ligands, especially 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.

Doel van het onderzoek

Several reports have indicated that the chemokine receptor CCR5 and its ligands, especially 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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Subjects with moderate/severe chronic plaque psoriasis 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.

Contactpersonen

Publiek

AMC,
polikliniek Huidziekten,
Meibergdreef 9,
M.A. Rie, de
Amsterdam 1105 AZ
The Netherlands
+00 31 20 5662585

Wetenschappelijk

AMC,
polikliniek Huidziekten,
Meibergdreef 9,
M.A. Rie, de
Amsterdam 1105 AZ
The Netherlands
+00 31 20 5662585

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Female subjects who are pregnant, intend to become pregnant, or are nursing;
2. Subjects who have taken methotrexate, cyclosporin or systemic retinoids within 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2004
Aantal proefpersonen:	32
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	24-01-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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