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SCH 351125: the effects of SCH 351125 on psoriatic plaque immuno-histochemistry, and chemokine expression in patients with moderate to severe psoriasis

Submission date	Recruitment status	[_] Prospectively registered
08/02/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/03/2021	Skin and Connective Tissue Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
P03657

Study information

Scientific Title
SCH 351125: the effects of SCH 351125 on psoriatic plaque immuno-histochemistry, and chemokine expression in patients with moderate to severe psoriasis

Study objectives
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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics board (Medical Ethics Committe AMC) on the 31st March 2004 (ref: 04/44).

Study design
Randomised, placebo-controlled, parallel group, double blinded multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Psoriasis

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

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
SCH 351125

Primary outcome measure
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 measures
1. Expression of chemokine messenger RiboNucleic Acid (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)

Overall study start date
01/04/2004

Completion date
01/12/2004

Eligibility

Key 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 (Psoriasis Area and Severity Index [PASI] more than eight) 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 cm^2 in size
4. The selected target lesions total numerical ratings for erythema, induration, and scaling must be at least six out of the possible nine using the following definitions for each sign: zero = none, one = mild, two = moderate, three = severe. The severity score for scaling must be at least two
5. Subjects clinical laboratory tests (Complete Blood Count [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 non-childbearing potential (I.e., sterilised via hysterectomy or bilateral tubal ligation or at least one year postmenopausal) or if of child bearing potential, must be practicing effective contraceptive methods from at least two weeks prior to day one and until 30 days following cessation of dosing
9. Female subjects of childbearing potential must have a negative serum pregnancy test (beta-human Chorionic Gonadotropin [hCG]) at screening

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
32

Total final enrolment
32

Key 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 within six weeks of treatment or topical anti-psoriasis 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 pre-existing 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 Human Immunodeficiency Virus (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

Date of first enrolment
01/04/2004

Date of final enrolment
01/12/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Schering-Plough B.V. (The Netherlands)

Sponsor details
Maarssenbroeksedijk 4-II
Utrecht
Netherlands
3542 DN

Sponsor type
Industry

Website
http://www.schering-plough.com/schering_plough/index.jsp

ROR
https://ror.org/05y28vr04

Funder(s)

Funder type
Industry

Funder Name
Schering-Plough

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2007	26/03/2021	Yes	No