The Effects of SCH 351125 on Mononuclear Cell Trafficking to Joints, Synovial Inflammation and Expression of Chemokines in Subjects With Rheumatoid Arthritis (Protocol No. P03653).

Gepubliceerd: 25-06-2007 Laatst bijgewerkt: 18-08-2022

SCH 351125 50 mg BID 2/days is an effective treatment for RA.

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24887

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Rheumatoide arthritis.

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 mononuclear cell migration into synovial tissue in subjects with rheumatoid arthritis;
2. to evaluate the safety and tolerability of multiple-dose administration of SCH 351125 50 mg twice-daily in subjects with rheumatoid arthritis when administered for 28 days.

Toelichting onderzoek

Achtergrond van het onderzoek

Thirty subjects with active rheumatois arthritis will be randomized in a double-blind, placebo-controlled, parallel-group study to either SCH 351125 50 mg BID or matched placebo, in a 2:1 ratio. Each treatment will be administered for 28 days.
Primary objectives of the study are to determine the effects of SCH 351125 on mononuclear cell migration into synovial tissue in subjects with rheumatoid arthritis, and to evaluate the safety and tolerability of multiple-dose administration of SCH 351125 50 mg twice-daily in subjects with rheumatoid arthritis when administered for 28 days.

Doel van het onderzoek

SCH 351125 50 mg BID 2/days is an effective treatment for RA.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Subjects with active rheumatoid arthritis (RA) 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

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Subjects 18 to 70 years of age, of either sex, and of any race;

2. Diagnosis of RA according to the American College of Rheumatology (ACR) criteria, for at least 6 weeks prior to entry in the study (see Appendix 6);

3. Active RA defined as: three or more tender joints, three or more swollen joints and at least one of the following three:

a. duration of morning stiffness equal to or greater than 45 minutes;

b. erythrocyte sedimentation rate equal to or greater than 28 mm/hr;

c. or C-reactive protein equal to or greater than 10 mg/L;

4. Functional Class I, II or III (see Appendix 6);

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

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

7. Females must not be breast-feeding, 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 double barrier contraceptive methods from at least 2 weeks prior to Day 1 and until 30 days following cessation of dosing;

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

9. Males must practice an effective barrier method of contraception from Day 1 until 30 days following cessation of dosing;

10. A physical examination must be without clinically significant findings with exception of those finding related to rheumatoid arthritis;

11. At Screening, ECG conduction intervals must be within the gender specific normal range (ie, QTc for males <430 msec and females <450 msec).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Individuals with a history of any significant medical disorder which require a physician's care (excluding rheumatoid arthritis) and would interfere with the study evaluations or compromise subject safety;

2. Individuals who have a history of any clinically significant local or systemic infectious disease within four weeks prior to drug administration;

3. Any subject with an allergy to gadolinium;

4. Any subject with a pacemaker, metal object implanted their body or any other device or condition which may interfere with a subject’s safety during the MRI procedure;

5. Any subject who has received DMARD treatment within 30 days prior to enrollment (leflunomide requires a charcoal or cholestyramine washout);

6. Any subject who has received anti-TNF therapy (except enteracept) or any biologic therapy within the previous 90 days;

7. Any subject whose baseline disease activity score (DAS28) (Appendix 6) has significantly changed since screening to indicate unstable disease;

8. Any individual who does not comply with the requirement that he should not have used; any drugs (including herbal and mineral supplements or vitamins), other than acetaminophen or an approved stable regimen of low dose prednisone (10 mg/day) and/or NSAIDS, for at least two weeks prior to study drug administration; alcohol in amounts of greater than 50 grams a day throughout the study;

9. Subjects that have been diagnosed with Juvenile RA (see Appendix 11);

10. A history of systemic lupus erythematosus, or signs and symptoms suggesting systemic lupus erythematosus;

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

12. Individuals who have participated in a clinical trial of an investigational drug within 90 days prior to the start of study drug administration, or have received prior treatment with a CCR5 receptor antagonist;

13. Individuals with a positive screen for drugs of abuse;

14. Individuals who have donated blood (>300 mL) within the preceding 90 days;

15. Males who are unwilling to use/practice an effective method of contraception (ie, condom in conjunction with spermicide from study start until 30 days after the last study treatment;

16. Females who are unwilling to use/practice an effective method of contraception (ie, condom in conjunction with spermicide from 2 weeks prior to study start until 30 days after the last study treatment;

17. Individuals who have received any vaccinations within 30 days prior to Screening;

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

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

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2004
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL977
NTR-old	NTR1005
Ander register	:
ISRCTN	ISRCTN87502236

Resultaten

Samenvatting resultaten

N/A