



Record 1 of 6



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COMPLETED ⓘ

AMG 714 20060349 Multiple Dose Study in Moderate to Severe Psoriasis Subjects

ClinicalTrials.gov ID ⓘ NCT00443326

Sponsor ⓘ Amgen

Information provided by ⓘ Amgen (Responsible Party)

Last Update Posted ⓘ 2016-01-20

Study Details Tab

Study Overview

Brief Summary

Feedback



Investigational drug AMG 714 will be given to 66 subjects with moderate to severe psoriasis to study safety, pharmacokinetics, and efficacy. Dose levels include 150mg and 300mg and will be given to each subject for a total of 6 doses. Each dose for each subject will be given once every 2 weeks. Subjects will followed for up to 300 days post the first dose of AMG 714.

Official Title

A Randomized, Double-blind, Placebo-controlled, Ascending Dose Study to Evaluate the Safety, Pharmacokinetics, and Efficacy of AMG 714 After Multiple Dose Administration in Subjects With Moderate to Severe Psoriasis

Conditions ⓘ

Psoriasis

Intervention / Treatment ⓘ

- Drug: AMG 714

Other Study ID Numbers ⓘ

- 20060349

Study Start ⓘ

2007-03

Primary Completion (Actual) ⓘ

2008-12

Study Completion (Actual) ⓘ

2010-05

Enrollment (Actual) ⓘ

22

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

[MedlinePlus](https://medlineplus.gov/) (<https://medlineplus.gov/>), related topics: [Psoriasis](https://medlineplus.gov/psoriasis.html) (<https://medlineplus.gov/psoriasis.html>).

[Other U.S. FDA Resources](https://classic.clinicaltrials.gov/ct2/info/fdalinks) (<https://classic.clinicaltrials.gov/ct2/info/fdalinks>).

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](https://clinicaltrials.gov/study-basics/learn-about-studies) (<https://clinicaltrials.gov/study-basics/learn-about-studies>).

Eligibility Criteria

Description

Inclusion Criteria:

- Active but clinically stable, plaque psoriasis.
- Psoriasis involving greater than or equal to 10% of the body surface area
- A minimum PASI score of 10 obtained during the screening period.
- Received at least one previous phototherapy or systemic psoriasis therapy or have been a candidate to receive phototherapy or systemic psoriasis therapy in the opinion of the investigator.
- At least 18 years of age.
- Heterosexually active men and women must be willing to practice an effective method of contraception (as outlined in section 6.7) as determined by the investigator and sponsor for the duration of the study. This includes any washout period and the follow-up period.
- ALT and AST less than or equal to 2 x the upper limit of normal; hemoglobin greater than or equal to 10 g/dL (greater than or equal to 100 g/L in SI units); platelet count greater than or equal to 125,000 mm³ (greater than or equal to 125 x10⁹/L in SI units); white blood cell count greater than or equal to 3,500 cells/mm³ (greater than or equal to 3.5 x10⁹/L in SI units); serum creatinine less than or equal to 2 mg/dL (less than or equal to 177 µmol/L in SI units).
- Negative for HIV antibodies, hepatitis B surface antigen, and hepatitis C antibodies.
- Capable of understanding and giving written, voluntary informed consent before study screening.

Exclusion Criteria:

- Active guttate, erythrodermic, or pustular psoriasis at the time of the screening visit.
- Evidence of skin conditions (eg, eczema) at the time of the screening visit or between the screening visit and study drug initiation that would interfere with evaluations of the effect of investigational product on psoriasis.
- Clinically significant adverse event, infection, or laboratory toxicity, at the time of the screening visit or between the screening visit and study drug initiation that in the opinion of Amgen or the Investigator would preclude participation in the study.
- Clinically significant infection less than or equal to 30 days before the screening visit that in the opinion of Amgen or the Investigator would preclude participation in the study.
- Known positive tuberculin skin test (if not treated with appropriate chemoprophylaxis) or recent (within 6 months) exposure to a patient with active tuberculosis.
- Any other known infectious process that would, in the investigator's discretion, interfere with the subject's ability to participate in the study.
- Significant concurrent medical conditions at the time of screening, including:
- Uncontrolled hypertension (defined as screening systolic blood pressure measurement of greater than 160 mm Hg or a screening diastolic blood pressure of greater than 100 mm Hg) confirmed by 2 separate measurements during the screening visit

- Myocardial infarction less than or equal to 52 weeks before the screening visit
- Unstable angina pectoris
- Congestive heart failure
- Steroid or oxygen dependent chronic obstructive pulmonary disease
- Diagnosis of multiple sclerosis or any other demyelinating disease
- Inadequately controlled diabetes mellitus, defined by glycohemoglobin greater than 7.0 at screening
- History of cancer (other than resected and surgically cured cervical cancer, cutaneous basal cell, squamous cell carcinoma) less than or equal to 5 years before the administration of first dose of investigational product
- Open cutaneous ulcers
- Any condition that, in the judgment of the investigator, might cause this study to be detrimental to the subject.
- Any evidence during screening of cutaneous basal or squamous cell carcinoma, or melanoma.
- Current or history of psychiatric disease that would interfere with the ability to comply with the study protocol or give informed consent.
- History of alcohol or drug abuse that would interfere with the ability to comply with the study protocol.
- Previous receipt of etanercept or any other anti-TNF agent(s), alefacept, efalizumab, or other investigational biologic agent for psoriasis.
- Receipt of any investigational product(s) less than or equal to 30 days before the first dose of investigational product in this study.
- PUVA therapy less than or equal to 30 days before the first dose of investigational product.
- UVA therapy less than or equal to 14 days before the first dose of investigational product.
- UVB therapy less than or equal to 30 days before the first dose of investigational product.
- Receipt of any other systemic psoriasis therapy or oral or parenteral corticosteroids less than or equal to 14 days before the first dose of investigational product.
- Topical steroids, topical vitamin A or D analog preparations or anthralin less than or equal to 14 days before the first dose of investigational product (exception - topical steroids at no higher than moderate strength, according to the package insert, are permitted on the scalp, axillae, and groin).
- Topical cyclosporin or calcineurin inhibitors such as pimecrolimus (Elidel) and tacrolimus (Protopic) less than or equal to 14 days before the first dose of investigational product.
- Intravenous or oral calcineurin inhibitors such as tacrolimus (Prograf) less than or equal to 30 days before the first dose of investigational product.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

What is the study measuring?

Primary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Psoriatic Assessment Score Index		First 85 Days

Secondary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Safety and Tolerability		Collected for 300 Days

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor ⓘ

Amgen

Collaborators ⓘ

No information provided

Investigators ⓘ

- Study Director: MD, Amgen

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

* Find [Publications about Study Results](#) and related [Pubmed Publications](#) in the “Results” section of the study record.

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted ⓘ
2007-03-01
First Submitted that Met QC Criteria ⓘ
2007-03-01
First Posted (Estimated) ⓘ
2007-03-05

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ
2015-12-16
Last Update Posted (Estimated) ⓘ
2016-01-20
Last Verified ⓘ

2015-12

More Information

Terms related to this study

Keywords Provided by Amgen

Psoriasis
PASI
Skin Biopsy
Human Monoclonal Antibody

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Drug and device information, study documents, and helpful links

Study Documents ⓘ

No study documents available

Helpful Links Provided by Amgen

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[AmgenTrials clinical trials website](http://www.amgentrials.com) (<http://www.amgentrials.com>)