A Phase 3, Multicenter, Randomized, Double-blind Study Comparing the Safety and Efficacy of ABT-874 to Methotrexate in Subjects with Moderate to Severe Chronic Plaque Psoriasis.

Published: 03-12-2007
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To compare the short-term and long-term clinical efficacy, safety and tolerability of ABT-874 compared to MTX in the treatment of moderate to severe chronic plaque psoriasis over a 24 and 52-week period.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON31792

Source
ToetsingOnline

Brief title
M10-255

Condition

- Epidermal and dermal conditions

Synonym
chronic plaque psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Abbott
Source(s) of monetary or material Support: Farmaceutisch bedrijf: Abbott GmbH & Co.K.G.

Intervention

Keyword: Chronic, Plaque, Psoriasis, Severe

Outcome measures

Primary outcome

Key study endpoints will be based on the Psoriasis Area and Severity Index

(PASI).

Secondary outcome

Other efficacy and quality of life parameters to be evaluated during the study

include the 6-point Physicians Global Assessment (PGA), Dermatology Life

Quality Index (DLQI), EQ-5D Health Questionnaire, Patient's Global Assessment

of Psoriasis-Severity, Psoriasis Related Pruritus Assessment, Visual Analog

Scale (VAS) for Plaque Psoriasis and Psoriatic Arthritis Pain, NAPSI, and NPGA.

Study description

Background summary

Psoriasis is a chronic immunologic disease characterized by marked inflammation and
thickening of the epidermis that results in thick, scaly plaques involving the skin. It
affects 1-3% of the general population, with the highest disease prevalence in North America and Europe.1 Psoriasis equally affects men and women, with peak onset
of symptoms in young adults and again in the mid 50's.

Psoriasis may be classified according to morphologic and clinical presentation:

plaque
psoriasis, guttate psoriasis, erythrodermic psoriasis, generalized pustular and localized
pustular psoriasis, and inverse or intertriginous psoriasis. Plaque psoriasis is the most
common form seen in 75-80% of psoriasis patients.

Treatment depends on the extent and severity of disease. Topical corticosteroids are
commonly used for mild to moderate cases. Other topical medications include keratolytic
agents, anthralin, coal tar, vitamin D analogs, and retinoids.5 For more widespread
disease, phototherapy (ultraviolet B [UVB] or ultraviolet A and psoralen [PUVA]) is
commonly used. Systemic therapy, including methotrexate (MTX), cyclosporine and synthetic retinoids are often effective in patients with moderate or severe disease.

Study objective

To compare the short-term and long-term clinical efficacy, safety and tolerability of ABT-874 compared to MTX in the treatment of moderate to severe chronic plaque psoriasis over a 24 and 52-week period.

Study design

This is a Phase 3, multi-center, randomized, double-blind, 2-arm controlled trial designed to evaluate the short-term and long-term safety and efficacy of of the human monoclonal antibody against IL-12/23 compared to MTX in subjects with moderate to severe chronic plaque psoriasis.

Intervention

This is a 52-week, double-blind, treatment period where subjects are randomized in a 1:1 ratio to receive either ABT-874 or MTX.

Study burden and risks

More than 300 subjects participating in Phase II clinical trials have ben treated with ABT-874. The majority of side effects experienced following administration of ABT-874 were mild and moderate in severity.
The most common side effects after administration of ABT-874 were mild and moderate: headache, nausea, worsening of symptoms of rheumatoid arthritis and the common cold and infections as nasopharyngitis (inflammation of the nose and throat) amd upper respiratory tract infections.

The most common side effects at the injection side: redness, itching, bruising, pain and/or irritation.Most injection side reactions were mild and usually went away within a few hours to a few days.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1.Males and females 18 years of age and over with diagnosis of stable moderate to severe plaque psoriasis for at least 6 months as determined by subject interview of his/her medical history and confirmation of diagnosis through physical examination by the Principal Investigator.
2. stable for at least 2 months before screening and at baseline
3. moderate to severe posriasis defined by >=10% Body surface Area (BSA) at baseline
4. PGA of at least moderate disease (defined as PGA >=3) at the baseline

5. PASI score of >= 12 at baseline
6. women childbearing potential must undergo monthly pregnancy testing during the study and agree to use two methods of contraception throughout the study, or postmenopausal for at least one year or sterile or hysterectomized;Subject is judged to be in good general health as determined by the Principal Investigator based upon the results of medical history, laboratory profile, physical examination, chest X-ray (CXR), and 12-lead electrocardiogram (ECG) performed at Screening.;Able and willing to give written informed consent and to comply with the requirements of this study protocol.

Exclusion criteria

1. previous exposure to systemic anti IL 12 therapy
2. previous exposure to MTX
3. diagnose of erythrodermic psoriasis, generalized or localized pustular psoriasis, medication induced or medication exacerbated psoriasis or new onset guttate psoriasis
4. history of an allergic reaction or sensitivity to constituents of study drug
5. Unable to discontinue not allowed topical or systemic therapies for the treatment of psoriasis such as corticosteroids, vitamin D analogs, UVB phototherapy or retinoids at least 2 weeks and PUVA phototherapy at least 4 weeks prior to the Baseline (Week 0) visit and during the study
6. cannot discontinue systemic therapies for the treatment of psoriasis
7. patient is taking or requires oral or injecttable corticosteroids
8. poorly controlled medical condition
9. history of clinically significant hematologic, renal or liver disease
10. patient has infection or risk factors for severe infections
11. history of malignancies other than successfully treated cell carcinoma
12. history of major immunologic reaction
13. exarcebation of asthma requiring hospitalization in the ten years prior screening
14. pregnant female or breast feeding or considering become pregnant
15. clinical significant abnormal lab. values
16. recent history of substance abuse or psychiatric illness
17. allergic hypersensitivity to MTX
18. rare hereditary problems of galactose intolerance

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2008
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Generic name:	Methotrexate
Product type:	Medicine
Brand name:	geen
Generic name:	geen
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	03-12-2007
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-02-2008
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	31-03-2008
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	10-04-2008
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-07-2008
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-08-2008
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-12-2008
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-03-2009
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-06-2009
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-08-2009
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-11-2009
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-12-2009
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2007-004687-47-NL
CCMO	NL20831.091.07