Methotrexate vs Azathioprine in Atopic Dermatitis: A 5 year follow up study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24759

Source
NTR

Brief title
MAcAD2

Health condition

atopic dermatits

Sponsors and support

Primary sponsor: Academic Medical Center, department of Dermatology
Source(s) of monetary or material Support: Academic Medical Center, department of Dermatology

Intervention

Outcome measures

Primary outcome

1. The primary efficacy variables are difference in mean change of the SCORAD and IGA between groups at different time points;

2. Also the comparison in the proportion of subjects with a SCORAD reduction of 50% or more

and the proportion of subjects with a IGA score of < 3 (clear / almost clear / mild) at different time points between MTX and AZA (Arm 1 and Arm 2).

Secondary outcome

1. Frequency and severity of Adverse Events;

2. Frequency of relapses.

Study description

Background summary

Atopic dermatitis is a chronic inflammatory skin disorder secondary to the activation of allergen specific T-cells in the skin. Most patients with AD can be treated effectively with emollients and topical anti-inflammatory agents such as topical steroids and topical calcineurin inhibitors. A subgroup of the AD patients, the more severe cases, require more than topical treatment to control their skin disease.

Cyclosporin (CsA) is considered gold standard for systemic treatment of severe AD and is highly effective. Many patients, however, are contra-indicated for CsA or have to discontinue treatment due to ineffectiveness or side effects such as hypertension and nephrotoxicity. It can be concluded that there is a very limited therapeutic armamentarium for the treatment of severe AD currently. Recent studies showed potential new systematic treatment options for severe AD. Two of which will be investigated in this study.
Our aim is to compare the efficacy and safety of methotrexate versus azathioprine treatment in adult patients with chronic severe AD. This study is 12-week single blind randomized controlled trial to evaluate the efficacy and safety of methotrexate (MTX) versus azathioprine (AZA) treatment in adult patients with chronic severe atopic dermatitis (AD) followed by a 5 year follow up study. Fourty- two patients were included and randomized to one of the treatment groups in a ratio of 1:1, and started there follow up after 12 weeks of treatment.

Study objective

We hypothezise that methotrexate and azathioprine will be equally effective for the treatment of severe atopic dermatitis.

Study design

1. Patients will be seen at random for screening at 2, 4, 8 or 12 weeks;

2. The follow up will will occur every 3, 6 to 12 months for 5 years.

Intervention

Methotrexate/Azathioprine.

Contacts

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Eligibility criteria

Inclusion criteria

1. Subject is 18 years of age or older at baseline; both genders;

2. Subject has a diagnosis of AD for at least 6 months based on millennium criteria (with or without IgE) and UK-criteria;

3. Subject has a score of 8-9 on the Rajka and Langeland Criteria which corresponds with a severity of ‘severe’;

4. Subject is candidate for systemic treatment for AD or clinical in-hospital treatment;

5. Subject is unresponsive, contra-indicated or intolerant to CsA treatment;

6. Female subject is either not of childbearing potential, defined as postmenopausal or surgically sterile or is of childbearing potential and practicing one of the following methods of birth control throughout the study until 3 months after receiving the last study agent:

A. Intrauterine device (IUD);

B. Contraceptives (oral, parenteral, patch) for three months prior to study drug administration;

C. A vasectomized partner.

7. Female subjects of childbearing potential must have a negative serum pregnancy test at the Screening visit and a negative urine pregnancy test at Baseline. Female subjects must not be nursing;

8. Sexually active male subjects are able to participate in the study if they / their partner use effective contraception (see 5) during the study and 3 months after discontinuation of the study drug;

9. Screening clinical laboratory analysis don’t show any of the following laboratory results: Aspartate transaminase (AST) or alanine transaminase (ALT) > 1.5 upper limit of normal (ULN), serum creatinine > 30 % of ULN and leucocytes or total white blood cell count < 3.0 x 10E9/L and Thiopurine methyltransferase below 48,9 µmol/gram of protein /hour only in treatment arm 2;

10. Subject has voluntarily signed and dated an informed consent prior to any study related procedure and is willing to comply with the requirements of this study protocol which has been approved by an Institutional Review Board (IRB/Independent Ethics Committee (IEC)).

Exclusion criteria

1. Subject is pregnant, nursing, or planning pregnancy (men and women) while enrolled in the study and until 3 months after discontinuation of the study;

2. Subject has used any investigational drug within the previous 4 weeks or 5 times the half-life of the investigational agent prior to the first administration of study agent, whichever is longer;

3. Subject has ever used AZA or MTX before;

4. Subject has received phototherapy or any systemic medications/treatments that could affect AD evaluation (including, but not limited to, oral or injectable corticosteroids) within the last 4 weeks of the first administration of study agent;

5. Subject has used very potent topical medications/treatments that could affect AD

evaluation within 2 weeks of the first administration of study agent;

6. A history of chronic or recurrent infectious diseases, including but not limited to chronic renal infection, chronic chest infection (eg, bronchiectasis), recurrent urinary tract infection (recurrent pyelonephritis or chronic nonremitting cystitis), or open, draining or infected skin wounds or ulcers;

7. A history of alcohol abuse;

8. A history of latent or active granulomatous infection, including TB, histoplasmosis or coccodioidomycosis;

9. Subject has or had herpes zoster infection within 2 months of study day 0;

10. Subject is known to be infected with HIV, hepatitis B, or hepatitis C;

11. Subject has a history or current signs or symptoms of severe, progressive, or uncontrolled renal, hepatic, hematological, gastrointestinal, endocrine, pulmonary, cardiac, neurological, cerebral, or psychiatric disease;

12. Subject has a transplanted organ (with exception of a corneal transplant > 3 months prior to the first administration of study agent);

13. A history of lymphoproliferative disease, including lymphoma, or signs and symptoms suggestive of possible lymphoproliferative disease, such as lymphadenopathy and/or splenomegaly;

14. Subject has any known malignancy or has a history of malignancy;

15. Subject has undergone allergy immunotherapy previously for prevention of anaphylactic reactions;

16. Subject participates in another trial using an investigational agent or procedure during participation in the trial;

17. Subject is dependent of a concomitant medication that has interaction with the study medication and thereby should be avoided. (APPENDIX M.);

18. For any reason, subject is considered by the local investigator to be an unsuitable candidate to participate in this trial.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-07-2009
Enrollment:	42
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-07-2009
Application type:	First submission

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
NTR-new	NL1806

Register	ID
NTR-old	NTR1916
Other	MEC Academic medical Center : MEC 09/143
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A