Myfortic in uveitis.

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At least comparable therapeutic efficacy of Myfortic as compared to ciclosporin in therapy refractory uveitis.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23540

Bron
Nationaal Trial Register

Verkorte titel
Myforic in Uveitis

Aandoening

Uveitis.

Ondersteuning

Primaire sponsor: JAM van Laar, ErasmusMC
Overige ondersteuning: Novartis BV, LSBS

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Total dose of prednisone.

Toelichting onderzoek

Achtergrond van het onderzoek

Title of the study:

Mycophenolate sodium (Myfortic) in the Treatment of Uveitis: a Pilot Study.

Background of the study:

Uveitis is a potentially sight threatening intraocular inflammation and responsible for 10 to 15% of patients with blindness. Non-infectious posterior uveitis is a presumed antigen-specific CD4+ T-lymphocyte–mediated autoimmune disease characterized by T-lymphocyte –and macrophage-induced and TNF-alpha mediated eye damage. Other cytokines involved in uveitis include IFN-γ, IL-1, 2, 5, 6, 10, 15, and TGF-β.

The T-cell inhibiting corticosteroids form the mainstay of immunoregulatory treatment in non-infectious uveitis. The second line drug of choice is cyclosporine, which exerts T-cell inhibitory actions. Its use may be limited by side effects such as impairment of the renal function, gastrointestinal complaints and hypertension.

Mycophenolate mofetil (MMF) inhibits the replication of T- and B-cells and also inhibits the local IL-15 dependent TNF formation. It is proven effective in patients with renal transplants, autoimmune diseases and uveitis. Side effects are relatively mild and seen in 10-30%. The enteric-coated formulation of mycophenolate sodium (EC-MPS, Myfortic®) is developed to overcome these side effects and is also proven effective in renal transplant recipients.

Objective of the study:

This study is designed to demonstrate equal therapeutic effect of Myfortic® as compared to MMF in this patient group, thus improving therapeutic efficacy.

Study design:

Single blinded randomized phase 4 trial.

Study population:

Steroid refractory patients with non-infetious uveitis older than 18 years.

Intervention (if applicable):

One group treated with Myfortic 720mg bid will be compared with ciclosporin 5 mg/kg/d in two doses.

Primary study parameters/outcome of the study:

Therapeutic equality between Myfortic® and cyclosporine:

1. Decrease of inflammatory response;

2. Improvement of BVCA;

Secundary study parameters/outcome of the study (if applicable):

Secondary endpoints:

1. Cystoid macular edema;

2. A possible relation with Inflammatory markers with therapeutic efficacy;

3. Adverse effects;

4. Total amount of steroids;

5. Time to relapse.

Doel van het onderzoek

At least comparable therapeutic efficacy of Myfortic as compared to ciclosporin in therapy refractory uveitis.

Onderzoeksopzet

Week 0, 2, 4, 8, 12, 16, 28, 40, 52.

Onderzoeksproduct en/of interventie

Treament with registered medication:

3 months of 1 mg/kg/d prednisone in tapering schedule + ciclosporine twice daily total 5mg/kg/d compared with same amount of prednisone + 720mg mycophenolaat sodium (Myfortic) twice daily. Hereafter 9 months of follow-up.

Contactpersonen

Publiek

Erasmus University Medical Center
Room D-419

J.A.M. Laar van
‘s Gravendijkwal 230

Rotterdam 3015 CE
The Netherlands
+31 (0)10 7035954

Wetenschappelijk

Erasmus University Medical Center
Room D-419

J.A.M. Laar van
‘s Gravendijkwal 230

Rotterdam 3015 CE
The Netherlands
+31 (0)10 7035954

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

1. Eligible patients with uveitis not responding to steroids due to:

a. Ocular sarcoidosis;

b. Intermediate uveitis;

c. Behçet’s syndrome;

d. Idiopathic Retinal Vasculitis;

e. Birdshot;

f. Vogt-Koyanagi-Harada disease;

g. Sympathetic ophthalmia;

h. Idiopathic panuveitis;

2. No systemic immunomodulatory agents other than steroids;

3. Significant flare requiring intensification of therapy (prednisone);

4. Visual acuity of 0.1 or better in at least one eye;

5. Adequate birth control measures;

6. The screening laboratory:

● Hemoglobin ≥ 6.5 mmol/L;

● WBC ≥ 3.0 x 109/L;

● Neutrophils ≥ 1.5 x 109/L;

● Platelets ≥ 100 x 109/L;

● SGOT and AF < 3 x ULN;

● Creatinine clearance > 20 ml/min;

7. Normal chest X-ray < 3 months;

8. Ability to adhere to the study visit schedule andprotocol requirements;

9. Capability of giving informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Inability to visualize the fundus;

2. Ocular surgery < 3 months of treatment;

3. Women who are pregnant, nursing, or planning pregnancy < 6 months;

4. Investigational drugs < 1 month or < 5 x T½;

5. Systemic immunosuppressive therapy, other than steroids for ocular disease;

6. Creatinine clearance of < 20ml/min;

7. Hypersensitivity to prednisone, cyclosporine, or Myfortic®;

8. Clinically significant infection;

9. Documented HIV infection;

10. Patients with active TB or evidence of latent TB;

11. Positive Lues serology and or significant Lues infection;

12. Oportunistic infections < 6 months;

13. Current signs or symptoms of severe organic disease;

14. Transplanted organ (except corneal transplant);

15. Malignancy < 5 years (except squamous or basal cell carcinoma of the skin);

16. Lymphoproliferative disease;

17. Substance abuse (drugs or alcohol);

18. Poor tolerability of venipuncture or lack of adequate venous access;

19. Recent live vaccinations.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-09-2007
Aantal proefpersonen:	24
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-11-2007
Soort:	Eerste indiening

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	NL1093
NTR-old	NTR1126
Ander register	ErasmusMC : METC: 2006-262 ABR: 14260 EUDRACT:2006-004709-24
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
Volgen.