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

Published: 15-03-2007
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This study is designed to demonstrate equal therapeutic effect of Myfortic® as compared to MMF in this patient group, thus improving therapeutic efficacy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ocular infections, irritations and inflammations
Study type	Interventional

Summary

ID

NL-OMON30290

Source
ToetsingOnline

Brief title
Myfortic in Uveitis

Condition

- Ocular infections, irritations and inflammations
- Immune disorders NEC

Synonym
inflammatory eye disease, uveitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Novartis

Intervention

Keyword: autoimmune, Myfortic, neoral, uveitis

Outcome measures

Primary outcome

Therapeutic equality between Myfortic® and cyclosporine:

§ Decrease of inflammatory response.

§ Improvement of BVCA

Secondary outcome

Secondary endpoints

§ Cystoid macular edema.

§ A possible relation with Inflammatory markers with therapeutic efficacy

§ Adverse effects.

§ Total amount of steroids.

§ Time to relapse

Study description

Background summary

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.

Study objective

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 3 trial

Intervention

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

Study burden and risks

No additional risk or burden will be caused by participation with this study. Medicines are registered for refractory autoimmune diseases and have been extensively used in the past.

Additionally 3 small vials of blood will be taken when blood tests are done during routine outpatient controles. There will not be any additional outpatinets controles

Contacts

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NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

patients with steroid refractory non-infectious uveitis

Exclusion criteria

1. fundus not visualizable opacities.
2. requiring ocular surgery < 3 months of treatment, or surgery in the prior 3 months.
3. pregnancy , nursing, or planning pregnancy within 6 months after screening (i.e., approximately 6 weeks following last treatment).
4. Use of any investigational drug within 1 month prior to screening or within 5 half-lives of the investigational agent, whichever is longer.
5. History of systemic immunosuppressive therapy, other than steroids for ocular disease.
6. Creatinine clearance of < 20ml/min.
7. Patients with known hypersensitivity to prednisone, cyclosporine, Myfortic® or to drugs with similar chemical structures.
8. Patients with any clinically significant infection.
9. Documented HIV infection.
10. Patients with active TB or evidence of latent TB.
11. Patients with opportunistic infections, including but not limited to evidence of active cytomegalovirus, active Pneumocystis carinii, Aspergillosis, Histoplasmosis or atypical mycobacterium infection, etc, within the previous 6 months.
12. Current signs or symptoms of severe, progressive or uncontrolled renal, hepatic, hematologic, gastrointestinal, endocrine, pulmonary, cardiac, neurologic, or cerebral disease.
13. Presence of a transplanted organ (with the exception of a corneal transplant 3 months prior to screening).
14. Malignancy within the past 5 years (except for treated squamous or basal cell carcinoma

of the skin without evidence of recurrence).
15. History of lymphoproliferative disease including lymphoma, or signs and symptoms suggestive of possible lymphoproliferative disease, such as lymphadenopathy of unusual size or location (such as nodes in the posterior triangle of the neck, infra-clavicular, epitrochlear, or periaortic areas), or splenomegaly.
16. Known recent substance abuse (drugs or alcohol).
17. Poor tolerability of venipuncture or lack of adequate venous access for required blood sampling during the study period.
18. Recent live vaccinations
19. Lues infection or serology

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-09-2007
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Myfortic
Generic name:	Mycophenolate sodium
Registration:	Yes - NL outside intended use
Product type:	Medicine

Brand name:	Neoral
Generic name:	cyclosporin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Prednisone
Generic name:	prednisolone
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-03-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-03-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-09-2007
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2006-004709-24-NL
CCMO	NL14260.078.06