Observational study; Mycophenolate sodium (Myfortic) in primary Sjogren’s syndrome.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28051

Source
Nationaal Trial Register

Brief title
N/A

Health condition

1. Sjogren's syndrome;

2. Mycophenolate sodium;

3. Sicca syndrome;

4. Immunosuppression.

Sponsors and support

Primary sponsor: Professor Dr. Markus Gaubitz
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Source(s) of monetary or material Support: Novartis Pharma GmbH, Nürnberg, Germany

Intervention

Outcome measures

Primary outcome

To evaluate the efficacy of mycophneolate sodium treatment in patients with pSS refractory to other immunosuppressive agents.

Outcome measures:

Glandular function tests, questionnaires, and laboratory tests at baseline, after 4 weeks, week 12, at week 24.

The lachrymal gland function will be assessed by unanesthetized Schirmer's test.

In addition, we will collected and weighed the unstimulated whole saliva throughout 5 minutes.

Visual analoge scale for the severity of ocular dryness, arthralgia, and fatigue on a 100-mm visual analogue scale (VAS) ranging from 0 to 100.

Outcome will also be determined by the Short Form-36 (SF-36). In addition, the Health Assessment Questionnaire (HAQ) has to be completed
Levels of immunoglobulins (IgG, IgM and IgA), RF-IgM as well as serum concentrations of complement levels (C3 and C4) will be measured during the trial. Also IgG antibodies to SS-A and SS-B will be analysed.

Secondary outcome

Safety of mycophenolate sodium treatment in patients with pSS:

Outcome measures:

History-taking including, clinical examination.

At each clinical visit, the patients will be asked about possible adverse events.

Laboratory tests at baseline, after 4 weeks, week 12, at week 24.(i.e. ESR, C-reactive protein (CRP), renal and liver function tests, total protein, and full blood count).

Study description

Background summary

Primary Sjogren’s syndrome (pSS) is an autoimmune disorder characterized by keratoconjunctivitis sicca and xerostomia. In addition, various extraglandular manifestations may develop. Several immunomodulating agents have been attempted in the treatment of pSS without achieving satisfactory results. Currently, there is no approved systemic treatment for pSS.

Since activation of lymphocytes is a key element in the pathogenesis of the disease inhibition of lymphocyte activation might be beneficial in the treatment of pSS. Mycophenolic acid has anti-proliferative effects on B- and T-cells.
Mycophenolate containing compounds such as mycophenolate mofetil (MMF) and enteric coated mycophenolate sodium (MPS) are immunosuppressive drugs approved for the prevention of transplant rejection. MPS 720 mg and MMF 1000 mg deliver nearly equimolar doses of the active immunosuppressive agent.
Although no controlled study has been performed so far mycophenoate has been suggested as sole or adjuvant treatment for primary Sjogren's syndrome pSS in a recent review articles.

The recent observations and the immunosuppressive effect of mycopenolate sodium in other autoimmune diseases led us to evaluate the efficacy and safety of Mycophenolate sodium treatment in patients with pSS refractory to other immunosuppressive agents.

Study objective

Mycophenolate is a selective inhibitor of inosine-monophosphate-dehydrogenase which leads to inhibition of the de novo pathway of nucleotide synthesis. The antiproliferative effect of mycophenolate mainly affects activated T- and B-lymphocytes because the proliferation of these cells is critically dependent on the de novo purine synthesis compared to other eukaryotic cells. Since these lymphocytes have been suggested to play a pivotal role in the inflammation and immunopathogenesis of primary Sjogren's syndrome, mycophenolate might be a promising agent in the treatment of pSS.

Study design

N/A

Intervention

The dosage of mycophenolate sodium shoud increase weekly by 360mg up to a maximum stable dose of 1440 mg daily. In patients not well tolerating the drug the dosage can be reduced to 720 mg per day.
Follow up visits will be after 4 week,

12 weeks and 24 weeks

Contacts

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Eligibility criteria

Inclusion criteria

1. Diagnosis of primary Sjogren's syndrome based on the American-European Consensus criteria (Vitali et al.);

2. Erythrocyte sedimentation rate >25mm/h and hypergammaglobulinemia (>1500 mg/dl);

3. Presence of anti-SS-A and /or SS-B antibodies and/or rheumatoid factor;

4. Requirement of artificial teardrops due to symptomatic sicca syndrome;

5. Adequate contraception for females of childbearing potential;

6. Inadequate response or intolerance of prior treatment with hydroxychloroquine and/or azathioprine.

Exclusion criteria

1. Age below 18 or above 75 years;

2. Pregnant or lactating women;

3. Secondary Sjogren’s syndrome;

4. History of cancer, severe infections or other uncontrolled diseases;

5. Treatment with concomitant disease modifying anti-rheumatic drugs within the least 4 weeks before baseline evaluation;

6. Prednisolone dose of >5mg/d or changes of prednisolone dose within the least 4 weeks before baseline;

7. Use of secretagogues (e.g. pilocarpine, civemeline) or medications that potentially diminish exocrine gland function (e.g. tricyclic antidepressants, anti-cholinergic drugs).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-04-2005
Enrollment:	11
Type:	Actual

Ethics review

Positive opinion

Date:	18-09-2007
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	NL1066
NTR-old	NTR1099
Other	: N/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

1. Gaubitz M, Schorat A, Schotte H, Kern P, Domschke W:
Mycophenolate mofetil for the treatment of systemic lupus erythematosus: an open pilot trial.
Lupus 1999, 8:731-736;
2. Willeke P, Domschke W, Gaubitz M: Mycophenolate Mofetil for the treatment of primary Sjögren's Syndrome: A case report. Ann Rheum Dis 2003, 62 (Suppl. 1) :352;
3. Mavragani CP, Moutsopoulos NM, Moutsopoulos HM: The management of Sjogren's syndrome.
Nat Clin Pract Rheumatol 2006, 2:252-261.