Estetrol Therapy in Sjögren’s Syndrome: An Open Proof of Concept

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22190

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Primary Sjögren’s syndrome

Sponsors and support

Primary sponsor: EMC
Investigator-initiated study
Source(s) of monetary or material Support: Pantarhei Bioscience (sponsoring study medication, pharmacy and review costs)

Intervention

Outcome measures

Primary outcome

Primary endpoint consists of a composite endpoint concerning meaningful improvement across 2 or 3 Sjögren’s syndrome disease domains: oral, ocular and laboratory test

Secondary outcome

Secondary endpoints include:

- improvement in quantitative levels of SSA and/or SSB

- decrease in pilocarpine use during treatment

- improvement in results of SF36

Study description

Background summary

Design:

An open, proof-of-concept, investigator initiated study

Subjects:

Female postmenopausal patients with primary Sjögren’s syndrome and complaints; no contraindications for estrogens especially no increased risk and/or history of thrombo-embolic events

Study Medication:

Estetrol, dose of 20 mg per day during 28 days.

Treatment regimen:

first 4 weeks run-in period with placebo, thereafter 4 weeks treatment with estetrol, followed by 14 days treatment with a progestogen.

Clinical phase:
Phase II (proof-of-concept)

Primary objective:

To explore overall response to treatment with estetrol in patients with primary Sjögren's syndrome.

Secondary objectives:

To assess:

· improvement in quantitative levels of SSA and/or SSB

· decrease in pilocarpine use during treatment.

· improvement in results of the SF36

· safety of estetrol treatment.

Primary Endpoints:

Primary endpoint consists of a composite endpoint concerning meaningful improvement across 2 of 3 Sjögren's syndrome disease domains: oral, ocular, and laboratory tests.

· Oral improvement will be defined as ≥20% in the patient's assessment of dry eyes (on a 100 mm VAS) or ≥20% improvement in total unstimulated salivary flow.

· Ocular improvement will be defined as ≥20% improvement in either the patient's assessment of dry eyes by VAS or the results of the Schirmer's test without anaesthetic.

· Laboratory improvement will be defined as ≥20% improvement in the serum IgG or the ESR.

Study objective

N/A

Study design

November/December - recruitment

First patient in: November 2008

Last patient out: March 2009

Intervention

20 mg estetrol per day during 28 days

Contacts

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Eligibility criteria

Inclusion criteria

1. Have the capacity to understand and willing to sign an informed consent form.

2. Fulfill American-European consensus criteria for primary Sjögren’s syndrome.

3. Postmenopausal women ≥ 18 and ≤ 70 years of age at the time of screening.

4. Body mass index ≥18 and ≤32 kg/m2.

5. Have complaints consistent with oral and ocular dryness.

6. The screening laboratory test results must meet the following criteria: SSA and/or SSB positive.

Exclusion criteria

1. Have a history of alcohol or substance abuse within the preceding 6 months.

2. Have a history of malignancy.

3. Have a history of trombo-embolic events or a positive lupus anticoagulant.

4. Have current signs or symptoms of severe, progressive or uncontrolled renal, hepatic, hematologic, gastrointestinal, endocrine, pulmonary, cardiac, neurologic, or cerebral disease.

5. Clinically significant abnormal results of routine hematology, serum biochemistry, urinanalysis, in the opinion of the Investigator at screening, and/or known ECG abnormalities.

6. Known clinically significant abnormal mammogram (presence of any non-cystic mass) within one year before study start.

7. Known clinically significant abnormalities of the uterus and/or ovaries detected earlier by examination and/or ultrasound.

8. A cervical smear with clinically relevant abnormal cytology within one year before study.

9. Previous use of estrogen/progestogen.

10. Use of hormone containing implant at any time.

11. Contraindications for using steroids.

12. Any enzyme affecting drugs from 30 days prior to Day 1 (see Appendix I) and the use of griseofulvin, phenytoin, barbiturates, carbamazepine, rimfampicin, nelfinavir, ritonavir, ketonazole, primidone, oxcarbazepine, topiramate, felbamate, herbal remedies containing hypericum perforatum (St. John’s wort).

13. Are unable or unwilling to undergo multiple venipunctures because of poor tolerability or lack of easy access.

14. Use of any investigational drug within 3 months prior to screening or within 5 half-lives of the investigational agent, whichever is longer.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-11-2008
Enrollment:	10
Type:	Actual

Ethics review

Positive opinion

Date:	06-11-2008
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	NL680
NTR-old	NTR1525
Other	: PR 3084
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A