PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

A Phase 1, Two Period, Double-blind, Randomised, Placebo-controlled, Cross- Over Study Investigating the Safety, Local Tolerability and Systemic Exposure of Cyclosporine A and Placebo (Vehicle) Following Single and Multiple Ocular Doses of CyclASol® and Placebo in Healthy Volunteers (CYS-001).

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

This study is intended to investigate the tolerability and the safety of Cyclosporine A containing CyclASol® eye drops compared to Placebo (vehicle) in a cohort of healthy volunteers. Subjects will be randomly assigned to dosing with CyclASol® eye drops or Placebo (vehicle) in the first part (first period) of the study, and switched to the alternative dosing in the second part (second period) of the study. An ophthalmological assessment of the eyes will be performed, and a questionnaire will be issued in the beginning and after each dosing. Additionally physical examinations, safety laboratory and ECGs will be performed, and blood samples will be analyzed for Cyclosporine A and Placebo (vehicle).

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00007194**
- Date of Registration in DRKS: **2015/06/10**

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Date of Registration in DRKS: **2015/06/10**

- Date of Registration in Partner Registry or other Primary Registry: **2014/04/07**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2013-005423-16**
- Primary Registry-ID: **NCT02113293 (ClinicalTrials.gov)**
- Sponsor-ID: **CYS-001 (Novaliq GmbH)**
- Other Secondary-ID: **2013-005423-16**

Health condition or Problem studied

- Free text: **Healthy**

Interventions/Observational Groups

- Arm 1: **Drug: CyclASol®**
- Arm 2: **Drug: Placebo (vehicle)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, caregiver, investigator/therapist, assessor**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Crossover**
- Phase: **I**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **patient/subject, caregiver, investigator/therapist, assessor**

Control: **Placebo**

Purpose: **Treatment**

Assignment: **Crossover**

Phase: **I**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Local tolerability measured by the rate and severity of drug-related adverse events of the eyes; time frame: 45 days; Multiple ophthalmologic assessments are performed in order to determine adverse effects of the investigational medicinal product on structures of the eye and its physiology.

Secondary Outcome

[---]*

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Neu-Ulm**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2014/03/31**
- Target Sample Size: **18**
- Monocenter/Multicenter trial: **[---]***
- National/International: **[---]***

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **45 Years**

Additional Inclusion Criteria

- Healthy male or female subject aged 18 - 45 years

- Nonsmoker, for at least three months prior to first dose of trial medication

- BMI from 18.5 to 29.9 (kg/m2)

- Corneal/Conjunctival staining Oxford grading = 0°

- Schirmer I more than 10 mm/5min

- Tear Film Break-Up Time (TFBUT) equal or more than 10 s

- Intra-ocular pressure between 10 and 20 mmHg

- Normal funduscopy

- Subject will have given their voluntary written informed consent to participate in the study in their own language and are willing to comply with the protocol

Exclusion criteria

- History of clinically relevant allergy (except for untreated, asymptomatic, seasonal allergies at time of dosing)

- History of dry eye disease, ocular surgery, corneal disease

- Known hypersensitivity to the drug substance

- Limbal stem cell deficiency

- Cicatricial pemphigoid

- Glaucoma or known steroid response on intraocular pressure

- Ocular allergy or incompatibility against Ciclosporin or semifluorinated alkanes

- Punctual occlusion

- Corrected vision with glasses less than 0.7 on one or both eyes

- Contact lens wear 3 weeks before to the planned first drug administration

and/or
during the study

- Acute infection of ocular surface (bacterial, viral, fungal...)

- Acute trauma of ocular surface

- No acceptable methods of birth control

- Pregnancy or breast-feeding period (females only)

- Use of any drugs whatsoever (including vitamins and herbals) for fourteen (14) days
prior to the planned first drug administration (excluding contraceptives in women and
single use of paracetamol or ibuprofen)

- Topical or systemic therapy with steroids, Ciclosporin, non-steroidal anti-inflammatory drugs, tetracyclines or other immunomodulatory substances within last 90
days prior to the planned first drug administration or during this trial

Addresses

■ **Primary Sponsor**

Novaliq GmbH

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Novaliq GmbH
Michael Beckert, MD

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Public Queries**

Novaliq GmbH
Michael Beckert, MD

Telephone: **[---]***
Fax: **[---]***

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Novaliq GmbH
Michael Beckert, MD

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/05/01**

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 1
- Last processed date by ClinicalTrials.gov: 2014/11/05

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*