# A Phase 1 Study to Evaluate the Safety and Tolerability of BYON5667 Eye Drops in Healthy Subjects

Published: 25-02-2021
Last updated: 17-01-2025

Primary objective:* To evaluate the safety of BYON5667 eye drops.Secondary objective:* To evaluate the tolerability of BYON5667 eye drops.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Eye disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON50780

**Source**
ToetsingOnline

**Brief title**
CS0364 Byondis

### Condition

- Eye disorders

**Synonym**
ocular side effects with ADCs

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Byondis B.V.
**Source(s) of monetary or material Support:** Byondis B.V.

## Intervention

**Keyword:** eye drops, safety, tolerability

## Outcome measures

### Primary outcome

Incidence of adverse events (AEs).

### Secondary outcome

Changes in ophthalmological examinations (i.e. visual acuity, slit lamp exam,

corneal sensitivity testing, and fluorescence tear film break-up time);

Tolerability scores (Ocular Comfort Index (OCI) and Visual Analogue Scale

(VAS)).

# Study description

### Background summary

Ocular side effects have emerged as an important clinical concern for molecularly targeted cancer therapies, despite these targeting therapies being more tumor selective than traditional systemic cytotoxic chemotherapy. In some cases these ocular side effects can be attributed to on-target effects due to target antigen expression in the eye, but, alternatively, toxicities may occur via off-target mechanisms and the etiology of such events is less clearly defined.
Byondis has developed a new-generation platform of linker-drugs (LD) in which the payload is based on chemically synthesized duocarmycins which are DNA-alkylating cytotoxic drugs [5] which induce cell death in both dividing and nondividing cells.
Byondis* aim is to improve the therapeutic index with ADCs based on these new LDs as compared to earlier generation ADCs. The first LD from this platform is valine-citrulline-seco-DUocarmycin-hydroxyBenzamide-Azaindole (vc-seco-DUBA) which is coded as SYD980. Currently three ADCs using this LD are in clinical investigation.
See the IB for further information.

### Study objective

Primary objective:
* To evaluate the safety of BYON5667 eye drops.
Secondary objective:
* To evaluate the tolerability of BYON5667 eye drops.

### Study design

This is a single center, randomized, placebo-controlled, double-blind study in healthy subjects.

### Intervention

BYON5667 or placebo eye drops

### Study burden and risks

Since the study is being executed in healthy volunteers, there are no anticipated benefits of the IMP. Please see the IB for further information.

## Contacts

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Byondis B.V.

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**Scientific**
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## Trial sites

### Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Healthy male and female subjects, aged from 18 to 75 years at the time of signing informed consent.
Presence of two functional eyes.
Good physical and mental health.
Female subjects of childbearing potential: an acceptable effective method of contraception must be used during the trial until the end-of-study (EOS ).

## Exclusion criteria

Presence or history of ocular disease or ocular trauma, or history of ocular surgery including laser-therapy, or ocular signs or symptoms of systemic disease , including current or prior pathology of eyelid or tear duct .
Amblyopia and color blindness are allowed.
Recent (within 2 months prior to signing informed consent) or current use of eye drops, or other (systemic) medication that may affect the eye according to the summary of product characteristics.
Use of contact lenses within 14 days before Day 1 and for the duration of the study.
Known active microbial, fungal or viral infection if deemed clinically significant by the investigator.
Subject is pregnant or lactating.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |

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| Control: | Placebo |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Completed |
| Start date (anticipated): | 18-03-2021 |
| Enrollment: | 32 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Nap. |
| Generic name: | Nap. |

## Ethics review

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| Approved WMO Date: | 25-02-2021 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 18-03-2021 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 06-06-2021 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 14-06-2021 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek |

(Assen)

# 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 | EUCTR2020-005574-10-NL |
| CCMO | NL76698.056.21 |

# Study results

Date completed: 13-09-2021

Results posted: 16-02-2022

**First publication**
01-02-2022