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# Panitumumab to prevent the progression of eyeball elongation in adults with nearsightedness and macular degeneration

**Submission date**
24/10/2022

**Recruitment status**
Recruiting

**Registration date**
03/03/2023

**Overall study status**
Ongoing

**Last Edited**
16/12/2025

**Condition category**
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
In experimental studies, antibodies injected into the back of the eye (intravitreal injections) against epidermal growth factor (EGF), EGF family members (amphiregulin, neuregulin-1, betacellulin, epigen, and epiregulin) and the EGF receptor (EGFR) were associated with a reduction in lens-induced axial elongation and in physiological eye elongation in guinea pigs and in non-human primates. Here we examined the intraocular tolerability and safety of a fully human monoclonal IgG2-antibody against EGFR, already in oncology in clinical use, as potential future therapy against axial elongation in adult eyes with pathological myopia. This study will evaluate the safety and tolerability of single and multiple intravitreal injections of panitumumab in adult highly myopic patients with myopic macular degeneration and characterize the pharmacokinetic and immunogenic potential.

Who can participate?
Patients aged 50 years old and under with nearsightedness and macular degeneration

What does the study involve?
Patients will receive intravitreal injections (into the back of the eye) of panitumumab (doses: 0.6 mg, 1.2 mg, or 1.6 mg) in intervals ranging between 1 month and several months. Patients will undergo repeated clinical and ophthalmological examinations.

What are the possible benefits and risks of participating?
The benefits of participating are the potential reduction in further axial elongation and thus a reduction of the risk of progression of myopic maculopathy. The risks are related to the injection, including the risk of infection which occurs after 1 in 3000 injections, and to the potential (yet unlikely) toxicity of panitumumab if applied intraocularly.

Where is the study run from?
Medical Faculty Mannheim of Heidelberg University (Germany)

When is the study starting and how long is it expected to run for?
November 2021 to December 2026

Who is funding the study?
Medical Faculty Mannheim of Heidelberg University (Germany)
Ufa Eye Research Institute (Russia)

Who is the main contact?
Prof Jost Jonas, jost.jonas@medma.uni-heidelberg.de (Germany)

# Contact information

### Type(s)
Principal investigator

### Contact name
Prof Jost Jonas

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
Nil known

# Study information

### Scientific Title
Intravitreal panitumumab for prevention of myopic axial elongation in highly myopic adult eyes with myopic macular degeneration

### Study objectives

In experimental studies, intravitreally applied antibodies against epidermal growth factor (EGF), EGF family members (amphiregulin, neuregulin-1, betacellulin, epigen, epiregulin) and against the EGF receptor (EGFR) were associated with a reduction in lens-induced axial elongation and in physiological eye elongation in guinea pigs and in non-human primates. The hypothesis is that the EGFR antibody panitumumab, already in oncology in clinical use, may be a potential therapy against axial elongation in adult eyes with pathologic myopia, if applied intravitreally.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 28/09/2021, the Ethics Committee of the Academic Council of the Ufa Eye Research Institute (Ufa Eye Research Institute, 90 Pushkin Street, Ufa 450077, Russia; +7 (347) 272 37 75; ufaeyenauka@mail.ru), ref: none available

## Study design
Single-center open-label multiple-dose phase I study

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Adult highly myopic patients with myopic macular degeneration

## Interventions
Any patient attending the Ufa Eye Research Institute and Hospital and fulfilling the inclusion criteria could be included in the study. The intervention will consist of intraocular injection of panitumumab (doses: 0.6 mg, 1.2 mg, or 1.6 mg) in intervals ranging between 1 month and several months. Re-injections will be performed every two months, under the condition (criteria) that the previous injections were well tolerated without observed intraocular or systemic side effects. Patients will be re-examined on the day of every injection and re-injection and at day 1 and day 7 after each injection. Follow-up is 6 months for each arm.

## Intervention Type
Biological/Vaccine

## Phase
Phase I

## Drug/device/biological/vaccine name(s)
Panitumumab

## Primary outcome(s)
Intraocular safety, defined by signs of intraocular inflammation, such as cells in the aqueous humour, increased Tyndall phenomenon, cells in the vitreous body, intraocular pressure, measured by slit lamp biomicroscopy of the anterior and posterior segment of the eye and applanation tonometry, at baseline and at every re-examination, i.e., at day 1 and 7 and at one and two months after each injection to search for signs of acute inflammation

### Key secondary outcome(s))
Axial length, measured by laser interferometric biometry at baseline, at every re-injection, and at the study end at 6 months

### Completion date
31/12/2026

## Eligibility

### Key inclusion criteria
1. Aged <50 years old
2. Axial length >26.0 mm
3. Myopic macular degeneration of stage 4 (foveal patchy atrophy)
4. Best corrected visual acuity >1.0 logMAR (logarithm of the minimal angle of resolution) (20 /200 Snellen equivalent)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
50 years

### Sex
All

### Total final enrolment
11

### Key exclusion criteria
Not meeting the inclusion criteria

### Date of first enrolment
05/11/2021

### Date of final enrolment
31/12/2025

## Locations

### Countries of recruitment

Russian Federation

**Study participating centre**
**Ufa Eye Research Institute**
90 Pushkin Street, Ufa 450077
Ufa
Russian Federation
450077

# Sponsor information

**Organisation**
Ufa Eye Research Institute

**ROR**
https://ror.org/04grwn689

# Funder(s)

**Funder type**
University/education

**Funder Name**
Ufa Eye Research Institute

**Funder Name**
Universitätsmedizin Mannheim

**Alternative Name(s)**
University Medical Centre Mannheim, Mannheim Üniversitesi Hastanesi, Университетская клиника Мангейм, Universitätsklinikum Mannheim, UMM

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
Germany

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available from the principal investigator upon reasonable request, Prof. Jost B. Jonas, Jost.Jonas@medma.uni-heidelberg.de. All measured and assessed data will be shared, in an anonymized format and will be available starting from the study end. Consent was required and obtained from participants and data anonymization was carried out in a standard manner.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 21/05/2024 | 16/12/2025 | Yes | No |