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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
12/12/2023

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
Axial length, measured by laser interferometric biometry at baseline, at every re-injection, and at the study end at 6 months

Overall study start date
01/11/2021

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

Age group
Adult

Upper age limit
50 Years

Sex
Both

Target number of participants
20

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
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Russian Federation
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Sponsor information

Organisation
Ufa Eye Research Institute

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Sponsor type
University/education

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

Publication and dissemination plan
Planned publication in a high-impact and peer-reviewed journal

Intention to publish date
31/12/2025

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