ISRCTN12733334 https://doi.org/10.1186/ISRCTN12733334

Treatment of dry, age-related macular degeneration by epidermal growth factor

Submission date
19/04/2020

Recruitment status
Stopped

Registration date
29/05/2020

Overall study status
Stopped

Last Edited
12/12/2023

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Age-related macular degeneration (AMD) is a common condition that affects the middle part of your vision. It usually first affects people in their 50s and 60s. It doesn't cause total blindness. But it can make everyday activities like reading and recognising faces difficult.
Pseudophakia follows eye surgery when an artificial lens replaces a person's natural lens.
The aim of the study is to investigate the effect of injecting a hormone into the eye to aid recovery after lens replacement.

Who can participate?
Patients aged 50+ years with pseudophakia, presence of geographic atrophy, normal intraocular pressure, lack of any other ocular disease except for age-related macular degeneration, and absence of any malignancy.

What does the study involve?
Participants will be randomly allocated to receive monthly injections of EGF (EberprotR) (experimental group) or pseudo-injection (control group) into the eye. The pseudo-injection includes the same preparations as for the true injection, with the only difference that an invasive procedure, i.e., the injection is not carried out. For three days after the injection and pseudo-injection, the eyes will receive eye drops 5x/day.
At baseline, at one month, three months and six months after baseline, the eyes will undergo an ophthalmological examination including refractometry, biometry, electroretinography, tonometry, and optical coherence tomography.

What are the possible benefits and risks of participating?
The potential benefits of the study and for the individual study participant in the study group are that for the time, a therapy may become available for the dry form of age-related macular degeneration

Where is the study run from?
Ufa Eye Research Institute (Bashkortostan, Russia)

When is the study starting and how long is it expected to run for?
April 2020 to December 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Jost Jonas
Jost.Jonas@medma.uni-heidelberg.de

Contact information

Type(s)
Scientific

Contact name
Prof Jost Jonas

ORCID ID
http://orcid.org/0000-0003-2972-5227

Contact details
Adenauerplatz 2
Heidelberg
Germany
69115
+49 6221 3929320
Jost.Jonas@medma.uni-heidelberg.de

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Epidermal growth factor for treatment of non-exudative age-related macular degeneration

Acronym
URPES-1

Study objectives
This study aims to assess the applicability, safety and efficacy of the intravitreal application of EGF (EberprotR) in patients with geographic atrophy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/11/2019, Ethics Committee of Ufa Eye Research Institute (90 Pushkin Street, Ufa 450008, Bashkortostan, Russia; +7 (347) 273-29-52; Ufnii-ethiccom@yandex.ru), ref: URPES-01

Study design
Clinical interventional prospective randomized double-masked study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Non-exudative age-related macular degeneration

Interventions
Participants will be randomly allocated to study or control groups using a random number selection method.

For each study participant of the study group, the eye with the worse best-corrected visual acuity will repeatedly receive intravitreal injections (50 µL) of EberprotR in a dose of 0.75ug /50µL or higher in intervals of 4 weeks.

For each study participant of the control group, the eye with the worse best-corrected visual acuity will repeatedly receive a pseudo-intravitreal injection in intervals of 4 weeks. The pseudo-injection includes the same preparations as for the true injection, with the only difference that an invasive procedure, i.e., the injection is not carried out.

For three days after the injection and pseudo-injection, the eyes will receive prednisolone acetate 1.0% eye drops in combination with a topical antibiotic (e.g. gentamicin eye drops or in combination) 5x/day.

At baseline, at one month, three months and six months after baseline, the eyes will undergo an ophthalmological examination including refractometry, biometry, electroretinography, tonometry, and optical coherence tomography.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Eberprot (recombinant epidermal growth factor [EGF])

Primary outcome measure
Size of geographic atrophies measured on fundus images obtained by optical coherence tomography at baseline, one month, three months and six months after baseline

Secondary outcome measures
At baseline, one month, three months and six months after baseline:
1. Visual acuity measured using by ophthalmologists or optometrists as best corrected visual acuity under standardized conditions and using modified Early Treatment of Diabetic Retinopathy Study (ETDRS) charts (Light House Low Vision Products, New York, NY) at a distance of 4 meters. If the optotypes cannot be read at a distance of 4m, one will continue with optotypes held at a distance of 1m. If the optotypes cannot be read at that distance the ability of finger counting and the detectability of hand movements at a distance of 1m or 50cm will be tested. If hand movements cannot be seen, the light perception with correct or incorrect projection will be assessed

Overall study start date
01/11/2019

Completion date
31/12/2023

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Age of 50 + years
2. Pseudophakia
3. Presence of geographic atrophy
4. Normal intraocular pressure
5. Lack of any other ocular disease except for age-related macular degeneration, and absence of any malignancy

Participant type(s)
Patient

Age group
Adult

Lower age limit
50 Years

Sex
Both

Target number of participants
60

Total final enrolment
7

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/04/2020

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
Russian Federation

Study participating centre
Ufa Eye Research Insitute
90 Pushkin Street
Ufa, Bashkortostan
Russian Federation
450077

Sponsor information

Organisation
Ufa Eye Research Institute

Sponsor details
90 Pushkin Street
Bashkortostan
Ufa

Russian Federation
450077
+7(347)272-37-75
Bikbov.m@gmail.com

Sponsor type
Hospital/treatment centre

Website
http://www.ufaeyeinstitute.ru/eng/

ROR
https://ror.org/04grwn689

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
01/04/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Prof. Mukharram Bikbov (Bikbov.m@gmail.com) and / or Prof. Jost B. Jonas (jost.jonas@medma.uni-heidelberg.de). They shall become available from June 2021 onwards. These data can then statistically be re-analyzed in an anonymized form, with consent from the study participants).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/07/2021	16/07/2021	Yes	No