

Acupuncture for eye diseases

Submission date 19/07/2021	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/09/2021	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/12/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The aim of this study is to assess the association between acupuncture and eye parameters such as intraocular pressure and visual acuity in patients with chronic eye diseases such as open-angle glaucoma and age-related macular degeneration.

Who can participate?

Patients aged over 18 years with stable eye disease

What does the study involve?

Participants are randomly allocated to one of two groups. The participants in the study group will undergo a standardized acupuncture procedure, while the participants in the control will undergo a sham acupuncture procedure, while their regular therapy remains unchanged. There are no drugs applied. The acupuncture sessions are performed weekly for 3 months, and after that every 3 weeks for a total study period of 8 months.

What are the possible benefits and risks of participating?

The possible benefits are an improvement in eye parameters such as intraocular pressure or visual acuity. There is no general risk due to acupuncture.

Where is the study run from?

Ufa Eye Research Institute (Russia)

When is the study starting and how long is it expected to run for?

August 2019 to December 2026

Who is funding the study?

Ufa Eye Research Institute (Russia)

Who is the main contact?

Prof. Mukharram M. Bikbov

Contact information

Type(s)

Scientific

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

1

Study information

Scientific Title

Acupuncture and ocular parameters: the Ufa acupuncture study

Acronym

UFaAcuStudy

Study objectives

Acupuncture may lead to a change in ocular parameters such as intraocular pressure and visual acuity, and to a change in systemic parameters, such as blood pressure and diabetic metabolic control (blood glucose concentration).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 12/12/2018, the Ethics Committee of the Academic Council of the Ufa Eye Research Institute (90 Pushkin st., Ufa, 450008, Russia; +7 (0)347 286 5303; niipriem@yandex.ru), ref: Protocol No 4

Study design

Case series study and a randomized controlled masked trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Ocular diseases such as glaucoma and age-related macular degeneration, and general diseases such as arterial hypertension and diabetes mellitus

Interventions

Randomisation will be performed as simple randomization using a random number generator. The participants in the study group will undergo a standardized acupuncture procedure, while the participants in the control will undergo a sham acupuncture procedure, while their regular therapy remains unchanged. There are no drugs applied. The acupuncture sessions are performed weekly for 3 months, and after that every 3 weeks for a total study period of 8 months.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Intraocular pressure measured by applanation tonometry at all acupuncture sessions performed weekly for 3 months, and after that every 3 weeks for a total study period of 8 months

Key secondary outcome(s)

Visual acuity measured using the best-corrected visual acuity method at all acupuncture sessions performed weekly for 3 months, and after that every 3 weeks for a total study period of 8 months

Completion date

31/12/2026

Reason abandoned (if study stopped)

Lack of staff/facilities/resources

Eligibility

Key inclusion criteria

1. Age >18 years
2. Not pregnant
3. Able to understand and sign a written informed consent

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

99 years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Age less than 18 years
2. Pregnancy
3. Unable to understand and sign a written informed consent

Date of first enrolment

01/09/2019

Date of final enrolment

31/12/2025

Locations**Countries of recruitment**

Russian Federation

Study participating centre**Ufa Eye Research Institute**

90 Pushkin Street

Ufa

Russian Federation

450077

Sponsor information**Organisation**

Ufa Eye Research Institute

ROR

<https://ror.org/04grwn689>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Ufa Eye Research Institute

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Mukharram M. Bikbov, Ufa Eye Research Institute, Pushkin st., Ufa, Russia, 450008.

Type of data that will be shared: Any kind of raw microdata.

When the data will become available and for how long: when the study is published, for several years.

The anonymized data will be shared with anybody requesting them.

Consent from participants was obtained.

IPD sharing plan summary

Available on request