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Acupuncture for eye diseases

Submission date 19/07/2021	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 06/09/2021	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 04/03/2024	**Condition category** Other	[ ] Individual participant data [ ] 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, available upon reasonable request from Jost.Jonas@medma.uni-heidelberg.de

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 measure
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

Secondary outcome measures
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

Overall study start date
01/08/2019

Completion date
31/12/2026

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

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

Sponsor details
c/o Prof. Mukharram Bikbov
90 Pushkin Street
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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/04grwn689

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ufa Eye Research Institute

Results and Publications

Publication and dissemination plan
The first results of the pilot study are to be published in late 2021 or 2022. A study protocol will be published together with the first results of a study.

Intention to publish date
01/02/2025

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