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Efficacy and safety of iontophoresis in patients with age-related cataract

Submission date	Recruitment status	[ ] Prospectively registered
30/01/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/03/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/08/2020	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cataracts are cloudy patches that develop in the lens of your eye and can cause blurred or misty vision. In many cases, cataracts are age-related, appearing first when a person is in his or her 40s or 50s, but not affecting vision until after age 60. Cataract surgery is the only treatment available while medical treatment is often provided but has proven to be not very effective. A safe and effective new technique is needed to improve patients' vision, especially for those with mild and moderate cataracts. Iontophoresis is a non-invasive technique in which a small electric current is applied to increase drug penetration into the tissues. The advantages are that it is easy to use and there are no systemic side effects. Based on the principle of iontophoresis, Suzhou Liu Liuliu Vision Science and Technology Co. developed a method to deliver traditional Chinese medicine with the iontophoresis device. Early results show that vision is improved after 4 weeks application of the treatment. The device has recently been approved by the Chinese FDA. The aim of this study is to evaluate the effectiveness and safety of iontophoresis in combination with traditional Chinese medicine in patients with age-related cataracts.

Who can participate?
Adults aged between 65 and 80 with age-related cataracts in both eyes and without any history of eye surgery or laser treatment.

What does the study involve?
Participants will be randomly assigned to receive either iontophoresis combined with traditional Chinese medicine or placebo (sham) treatment. They will be followed up regularly for 4 weeks and during each visit there will be a series of vision assessments. The safety and effectiveness of iontophoresis will be estimated by changes in lens opacity, visual acuity, visual satisfaction and complications.

What are the possible benefits and risks of participating?
All of the participants in the study will receive a series of close follow-ups of their ocular health for 4 weeks with traffic subsidies. All of the participants will also receive an iontophoresis apparatus upon completion. The main benefit of iontophoresis is that it can potentially improve

vision and reduce the density of cataract. The main risk of participating is that the Chinese medicine may cause an allergic reaction on the eyelids in some cases. In this case, it will not affect vision in the majority of cases, but severe allergy may require medical treatment.

Where is the study run from?
The study will be carried out at the Department of Preventive Ophthalmology, Zhongshan Ophthalmic Center (China).

When is the study starting and how long is it expected to run for?
Recruitment of the study started in December 2014. Each participant will be in the study for 4 weeks and the study is expected to run until May 2015.

Who is funding the study?
1. Zhongshan Ophthalmic Center, Department of Prevention Ophthalmology
2. Suzhou Liuliu Vision Science and Technology CO., LTD

Who is the main contact?
Mingguang He
mingguang_he@yahoo.com

Contact information

Type(s)
Scientific

Contact name
Dr Mingguang He

Contact details
54Xianlie S RoadYuexiu
Guangzhou
China
510060
+86 (0)20 87331109
mingguang_he@yahoo.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Efficacy and safety of iontophoresis in patients with age-related cataract: a single-center, randomized, double-masked, controlled trial

Study objectives
Patients with age-related cataract can obtain a better visual function after iontophoresis treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
All procedures in this study adhered to the tenets of the Declaration of Helsinki and were approved by the Research Ethics Committee of Zhongshan Ophthalmic Center, Sun Yat-Sen University, China, 27/01/2014, certification number 2013MEKY031

Study design
Randomized double-blinded placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Age-related cataract

Interventions
Experimental arm: Use energized iontophoresis therapeutic apparatus combined with traditional Chinese medicine eye patch 30 minutes a day for 4 weeks.
Controlled arm: Use non-energized iontophoresis therapeutic apparatus combined with placebo eye patch 30 minutes a day for 4 weeks.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
1. Change of uncorrected visual acuity, measured by ETDRS chart at baseline, 1 week, 2 weeks, 3 weeks and 4 weeks
2. Change of best-corrected visual acuity, measured by ETDRS chart at baseline, 1 week, 2 weeks,

3 weeks and 4 weeks
3. LOCS III lens opacity grading, measured by slit-lamp examination at baseline, 2 weeks and 4 weeks

Secondary outcome measures
1. Photographic evaluation of a change from baseline in nuclear, cortical, or posterior subcapsular cataract opacity grades, measured according to LOCSIII at baseline, 2 weeks and 4 weeks
2. Lens density varies during 4 weeks follow-up measured by Pentacam at baseline, 2 weeks and 4 weeks
3. Adverse events within 4 weeks associated with iontophoresis and traditional Chinese medicine.
4. Visual satisfaction, measured by questionnaire at 4 weeks

Overall study start date
01/01/2014

Completion date
01/06/2015

Eligibility

Key inclusion criteria
1. Adults between the ages of 65 and 80 years old
2. LOCS III nuclear opalescence score >=3.0 OR cortical cataract score >=3.0 OR posterior subcapsular score >=1.0 bilateral
3. Able to commit to the 4-week follow up
4. Able to understand and sign an informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
118

Key exclusion criteria
1. Types of cataracts other than age-related, including metabolic cataract, drugs and toxic cataract, congenital cataract, etc
2. Any other ocular pathology that may affect visual acuity, such as glaucoma, uveitis and retinopathy, etc
3. Patients with inflammation of the ocular surface and the adjacent area
4. History of ocular surgery or laser

5. Patients who are blind in one eye
6. Patients with uncontrolled systemic disease, i.e. high blood pressure (Bp > 160/100 mmHg), diabetes mellitus (GLU-AC >8mg/dl), kidney disease, etc

Date of first enrolment
01/12/2014

Date of final enrolment
18/02/2015

Locations

Countries of recruitment
China

Study participating centre
Zhongshan Ophthalmic Center
54, Xianlie S Road
Guangzhou
China
510060

Sponsor information

Organisation
Zhongshan Ophthalmic Center

Sponsor details
Department of Prevention Ophthalmology
54, Xianlie S Road
Yuexiu
Guangzhou
China
510060

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0064kty71

Funder(s)

Funder type
Industry

Funder Name
Zhongshan Ophthalmic Center

Funder Name
Suzhou Liuliu Vision Science and Technology CO., LTD

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request