

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Micropulse Transcleral Cyclophotocoagulation in the treatment of refractory glaucoma

#### Protocol summary

##### Study aim

To lower the intraocular pressure in patients with refractory glaucoma

##### Design

Open label, non randomized, non comparative trial

##### Settings and conduct

Patients were selected consecutively, when fulfilling the trial criteria. afterwards the laser procedure was done by one surgeon and the evaluation performed 12 months, after 1 week, 1 month, 3 months, 6 months and one year. At each visit, there were a series of ocular measurements and investigations done. All ocular determinations were saved and compared.

##### Participants/Inclusion and exclusion criteria

100 participants. Inclusion: IOP > 21 mmHg, Age > 18 years, signed informed consent. Exclusion: uveitis, history of ocular surgery in the last 3 months

##### Intervention groups

We apply the micropulse laser probe next to the limbus, and firmly slide the probe along the limbus. The laser is delivered in a micropulse way to the ciliary body, increasing the outflow way, lowering the IOP

##### Main outcome variables

IOP, medication number used before laser and after laser, patient's pain felt during the procedure, laser parameters

#### General information

##### Reason for update

##### Acronym

mTSCPC

##### IRCT registration information

IRCT registration number: **IRCT20170325033136N2**

Registration date: **2018-05-18, 1397/02/28**

Registration timing: **prospective**

Last update: **2018-05-18, 1397/02/28**

Update count: **0**

##### Registration date

2018-05-18, 1397/02/28

##### Registrant information

###### Name

Alexandra Preda

###### Name of organization / entity

Centrul Oftalmologic Prof Dr Munteanu

###### Country

Romania

###### Phone

0040745113511

###### Email address

alexandrapreda004@gmail.com

##### Recruitment status

**Not yet recruiting**

##### Funding source

##### Expected recruitment start date

2637-09-11, 2016/06/20

##### Expected recruitment end date

2639-03-11, 2017/12/20

##### Actual recruitment start date

2637-09-23, 2016/07/01

##### Actual recruitment end date

2639-03-06, 2017/12/15

##### Trial completion date

empty

##### Scientific title

Micropulse Transcleral Cyclophotocoagulation in the treatment of refractory glaucoma

##### Public title

Micropulse Transcleral Cyclophotocoagulation in the treatment of refractory glaucoma

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Intraocular pressure higher than 21 mmHg Age > 18

Signed informed consent

**Exclusion criteria:**

Uveitis Ocular surgery in the last 3 months, prior to study enrolment.

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

Actual sample size reached: **100**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Other

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

The ethics committee of the Ophthalmologica

**Street address**

B dul 3 August nr 2, Timisoara

**City**

Timisoara

**Postal code**

300668

**Approval date**

2637-09-06, 2016/06/15

**Ethics committee reference number**

1/01.06.2016

## Health conditions studied

### 1

**Description of health condition studied**

Glaucoma, IOP

**ICD-10 code**

H40.9

**ICD-10 code description**

Unspecified glaucoma

## Primary outcomes

### 1

**Description**

IOP decrease

**Timepoint**

1 week, 1 month, 3 months, 6 months, 1 year

**Method of measurement**

Goldman applanationometry

## Secondary outcomes

### 1

**Description**

Pain endurance

**Timepoint**

5 minutes after procedure

**Method of measurement**

VAS scale

### 2

**Description**

Number of eye drops after the procedure to control the IOP

**Timepoint**

1 month, 6 months, 1 year

**Method of measurement**

Asking patient

## Intervention groups

### 1

**Description**

Intervention group: the intervention group is consisted of the nontreated eye. In each patient only one eye is treated with micropulse cyclophotocoagulation, the fellow eye represents control group. The treated group, consisted of the treated eye, underwent one session of micropulse transcleral cyclophotocoagulation (mTSCPC), after which standard eye drops were prescribed for 2 weeks. The treatment consisted of cyclopentolate, cortison (fluorometolona) and antibiotic (netilmicina). The glaucoma treatment was never interrupted. The protocol included retrobulbar anesthesia with 1:1 mixture of 0.75% bupivacaine and 4% lidocaine and intravenous sedation (fentanyl/propofol), according to the patients' pain tolerance. Laser settings were 2000 mW of 810 nm infrared diode laser set on micropulse delivery mode. The laser was delivered over 360° for 160-260 ms. The duty cycle was 31.3 %, which translated to 0.5 ms of "on time" and 1.1 ms of "off time". The probe was applied in a sweeping motion, keeping firm pressure and moved from 10 o'clock to 2 o'clock for the superior quadrant, and from 4 o'clock to 8 o'clock for the inferior quadrant. The 3 and 9 o'clock areas and also any area of thinned sclera were avoided. Examinations were performed at 1 week, 1 month, 3 months, 6 months and 12 months after the procedure,

and included anterior segment examination, anterior chamber reaction, and Goldmann applanation tonometry. All the ocular determinations were made between 9 and 11 am. We monitored intraocular pressure, best corrected visual acuity (BCVA), number and type of medications used. The device is called MicroPulse® P3 Glaucoma Device (MP3) IRIDEX. we want to compare the intraocular pressure of the treated eye before the mTSCPC and how much it dropped, after one year. We also compare with the nontreated eye, and if the laser had any influence on the nontreated eye, considering the sympathetic connection between the eyes. The treated group consists 100 eyes, and the nontreated group, 100 eyes, the fellow eye.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Oftalmologica SRL

##### Full name of responsible person

Maria Alexandra Preda

##### Street address

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##### City

Timisoara

##### Postal code

300668

##### Phone

+40 256 496 336

##### Email

Alexandrapreda004@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Alexandra Preda

##### Full name of responsible person

Alexandra Preda

##### Street address

B dul 3 August nr 2

##### City

Timisoara

##### Postal code

300668

##### Phone

+40 256 496 336

##### Email

superstarale@yahoo.com

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Alexandra Preda

##### Proportion provided by this source

10

##### Public or private sector

Private

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

Persons

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Centrul Oftalmologic Prof Dr Munteanu

##### Full name of responsible person

Alexandra Preda

##### Position

Ophthalmologic clinic

##### Latest degree

Specialist

##### Other areas of specialty/work

Ophthalmology

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Clinica Prof Dr Munteanu

##### Full name of responsible person

Alexandra Preda

##### Position

Specialist

##### Latest degree

Specialist

##### Other areas of specialty/work

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Clinica Prof Dr Munteanu

**Full name of responsible person**

Alexandra Preda

**Position**

Specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Ophthalmology

**Street address**

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**City**

Timisoara

**Province**

Timis

**Postal code**

300668

**Phone**

+40 745 113 511

**Email**

superstarale@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

This are confidential and personal information

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Inform consent

**When the data will become available and for how long**

12.2018

**To whom data/document is available**

Everybody interested in ophthalmology field

**Under which criteria data/document could be used**

Ciclophotocoagulation laser

**From where data/document is obtainable**

Our clinic

**What processes are involved for a request to access data/document**

Demand, waiting time

**Comments**