Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Micropulse Transcleral Cyclophotocoagulation in the treatment of refractary glaucoma

Protocol summary

Study aim
To lower the intraocular pressure in patients with refractary glaucoma
Design
Open label, non randomized, non comparative trial
Settings and conduct
Patients were selected consecutively, when fullfilling the trial criteria.afterwards the laser procedure was done by one surgen and the evaluation performed 12 months, after 1 week, 1 month, 3 months,6 monts 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 culiary body, increading 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
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Romania
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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 refractary glaucoma

Public title
Micropulse Transcleral Cyclophotocoagulation in the treatment of refractary 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 Ophtalmologica

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 aplanotonometry

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 ciclopentolate, cortison (fluorometolona) and antibiotic (netilmicina). The glaucoma treatment was never interupted. 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 comapre 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 gropus, 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Ophtalmologic clinic

Latest degree
Specialist

Other areas of specialty/work
Ophthalmology

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Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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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