Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Oct 2023

The efficacy of oral pain relief cocktail during panretinal photocoagulation for diabetic retinopathy: a randomized clinical trial

Protocol summary

Study aim

The efficacy of oral pain relief Combination analgesic drugs during panretinal photocoagulation for diabetic retinopathy , Pain sensation was evaluated with Visual Analogue Scale (VAS), Changes in blood pressure and pulse

Design

The clinical trial has a control group with cross over, double-blind, randomized groups using randomization table, phase 2-3 on 30 patients.

Settings and conduct

Motahari clinic is located in Shiraz University of Medical Sciences. We divide each patient into four parts (ST/SN/IT/IN) and in each session one area of each eye of the patient is lasered, for example: the patient receives novafen capsule alone in the first session, in the second session, pregabalin capsule and in the third session he receives two drugs and in the fourth session he receives placebo.

Participants/Inclusion and exclusion criteria

age: years old bilateral proliferative diabetic retinopathy or severe non-proliferative diabetic retinopathy no previous laser treatment best corrected visual acuity of 20/200 or better intraocular pressure under 21 mmHg spherical equivalent of ± 5.00 diopters clear media and vitreous

Intervention groups

30 patients with NPDR or SNPDR who go to laser clinic by explaining the research plan for patients and their satisfaction. In this plan, each patient's retest is divided into four parts (ST/SN/IT/IN) and in each session one area of each eye of the patient is lasered;Each visit is used in a different way to reduce the patient's pain during laser, for example: the patient receives novafen capsules alone in the first session of the visit, in the second session, the pregabalin capsule and in the third session, the combination of two drugs and in the fourth session placebo will receive placebo.

Main outcome variables

patient scored the pain sensation immediately after each PRP section using Scott& rsquo s visual analogue scale (VAS).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200915048724N1**
Registration date: **2020-10-29, 1399/08/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-29, 1399/08/08**
Update count: **0**

Registration date

2020-10-29, 1399/08/08

Registrant information

Name

Mohammadkarim johari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 2830

Email address

mkjoharii@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-05-20, 1400/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of oral pain relief cocktail during panretinal photocoagulation for diabetic retinopathy: a randomized clinical trial

Public title

The efficacy of oral pain relief cocktail during panretinal photocoagulation for diabetic retinopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age: years old proliferative diabetic retinopathy severe non-proliferative diabetic retinopathy no previous laser treatment best corrected visual acuity of 20/200 or better intraocular pressure under 21 mmHg spherical equivalent of ± 5.00 diopters clear media and vitreous severe non-proliferative diabetic retinopathy

Exclusion criteria:

previous photocoagulation treatment media opacity such as cataracts, corneal diseases or vitreous hemorrhage unilateral PDR chronic use of analgesics history of any side effects related to pregabalin or novafen Myopic more or equal to 6 Renal Failure

Age

From **51 years** old to **69 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

both eyes of each patient

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method using a table of random numbers has been used. 30 patients are included in this study. Depending on the time of enrollment, a number from 1 to 30 is assigned to each patient. Each patient needs four sessions of laser treatment. Also, for each patient, four pain relief interventions are considered, which are marked with the letters A, B, C, D. For each laser treatment session, based on the table of random numbers in the first row from left to right, the last two digits and the number 00-24 for intervention A and 25-49 for intervention B and 50-74 for intervention C and 75-99 for intervention D are considered. After determining the sequence of interventions for 30 patients, opaque envelopes were used for concealment. The order of interventions is placed on cards in the envelope and each envelope is assigned to one patient. During the treatment, a third person delivers the analgesic drug to the patient based on this sequence before the laser.

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study is an interventional double-blind randomized clinical trial in which a specialist and patient will not know the type of medication received at each stage.Each patient will be given numbers from 1 to 30 and each number will be entered in the randomization table and according to the table, one of the four treatment plan will be performed at each patient's visit. The nurse who delivers the drug to the patient according to the randomization table is aware of the type of medication.The data collector and those who assess the outcome are unaware of the type of drug used.

Placebo

Used

Assignment

Crossover

Other design features

Oral medications were given one hour before PRP. Pain sensation is assessed immediately after treatment by verbal rating scale, which is a useful clinical pain index for pain intensity in postoperative patients. The verbal scale included a range of 0 (painless in all), 1 (slight discomfort), 2 (mild pain), 3 (moderate pain), 4 (severe pain), up to 5 (very painful). Blood pressure and heart rate are recorded by a digital blood pressure monitor 15 minutes before and immediately after treatment. Before laser treatment, measurements are performed after rest for at least 15 minutes. The statistics of the variables described as standard mean and deviation are expressed. The retin of each patient entering the study is divided into four regions :(ST/SN/IT/IN) and one area of two eyes is lasered in each session. According to the random table, each patient will be given one of the four treatment plan before laser and the patient's pain will be recorded immediately.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences central building, Zand BLVD, Shiraz,

City

shiraz

Province

Fars

Postal code

7134814336

Approval date

2020-09-21, 1399/06/31

Ethics committee reference number

IR.SUMS.MED.REC.1399.360

Health conditions studied

1

Description of health condition studied

prolifrative Diabetic retinopathy-non prolifrative Diabetic retinopathy

ICD-10 code

E08.321

ICD-10 code description

Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema

Primary outcomes

1

Description

Pain in VAS Questionnaire

Timepoint

patient scored the pain sensation immediately after each PRP section using Scott& rsquo s visual analogue scale (VAS).

Method of measurement

visual analogue scale (VAS).

Secondary outcomes

1

Description

Blood pressure

Timepoint

Blood pressure were taken by a digital blood pressure monitor 15 min before and immediately after laser treatment.

Method of measurement

digital blood pressure monitor

Intervention groups

1

Description

Intervention group: At first, 30 patients (60 eyes) are studied, each patient's retin is divided into four parts and in each session one area of each eye is lasered one hour before the laser according to the drug randomization table is given to the patient. This drug can be placebo, navafen,150mg capsule combination of navafen and150mg capsule pregabalin.The patient's pain sensation will be measured immediately after each PRP ward using the Visual AnalogUe Scale (VAS). In four sessions for laser one-quarter retin, he receives three sessions of analgesics and in one placebo session.

Category

Treatment - Surgery

2

Description

Control group: In this study, each patient receives three sessions of analgesics in four sessions for one-quarter retin laser and in one placebo session.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Clinic, Shiraz University of Medical Sciences

Full name of responsible person

Mohammad karim Johari

Street address

Shiraz University of Medical Sciences central building, Zand BLVD, Shiraz,

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5410

Email

mkjoharii@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad karim Johari

Street address

Shiraz University of Medical Sciences central building, Zand BLVD, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5410

Email

mkjoharii@gmail.com

Grant name

Shiraz University of Medical Sciences

Grant code / Reference number

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

Title of funding source
Shiraz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mohammad hossein norouzzade

Position
associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Ophthalmology

Street address
Shiraz University of Medical Sciences central building, Zand BLVD, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
7134814336

Phone
+98 71 3230 5410

Email
mkjoharii@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mohammad karim Johari

Position
associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Ophthalmology

Street address
Shiraz University of Medical Sciences central building, Zand BLVD, Shiraz,

City
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Fars

Postal code
7134814336

Phone
+98 71 3230 5410

Email
mkjoharii@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mohammad karim Johari

Position
associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Ophthalmology

Street address
Shiraz University of Medical Sciences central building, Zand BLVD, Shiraz, Iran

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Province
Fars

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7134814336

Phone
+98 71 3230 5410

Email
mkjoharii@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All potential data is shareable after people are identified

When the data will become available and for how long
Start of access period 6 months after printing results

To whom data/document is available
Researchers working in academic and scientific institutions and people who are also engaged in the

industry

Under which criteria data/document could be used

No other terms for using data or documentation

From where data/document is obtainable

mkjoharii@gmail.com Mohammad karim Johari

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

Send request to introduced email

Comments