NCT Number: **Date:** 24/02/2024

Official Title

Comparison of peroperative methotrexate infusion with postoperative intra silicon oil methotrexate injections for prevention of proliferative vitreoretinopathy development after vitrectomy for rhegmatogenous retinal detachment repair.

This **informed consent form (ICF)** is for retinal detachment patients who are invited to participate in research that will be conducted in Sahiwal Teaching Hospital, Sahiwal and Ali Fatima Teaching Hospital Lahore from March 2024 to May 2025.

Name of principal investigator: Dr. Ahmad Zeeshan Jamil

Name of Co-investigator: Dr Muhammad Hannan Jamil

Name of institute:-

- Sahiwal Teaching Hospital, Sahiwal / University of health sciences Lahore, Pakistan
- Ali Fatima Teaching Hospital Lahore / Green International University Lahore, Pakistan

This informed consent form has two parts:

- Information sheet (to share information about research with patients)
- Certificate of consent (for signature if patients agree to take part)

Patients will be given a copy of the full informed consent form.

Part 1: Information Sheet

Introduction

I am Dr. Ahmad Zeeshan Jamil working as professor of ophthalmology in Sahiwal Medical College & Sahiwal Teaching Hospital, Sahiwal. I am doing research on Comparison of peroperative methotrexate infusion with repeated post operative intra silicon oil methotrexate injections for the prevention of proliferative vitreoretinopathy development after pars plana vitrectomy for rhegmatogenous retinal detachment repair. I am inviting you to participate in the research. You can talk to anyone you feel comfortable talking with about the research. You can take time to decide whether you want to participate in the research or not. If you do not understand some of the words or concepts then I am available to explain.

Purpose of the research

Proliferative Vitreoretinopathy (PVR) is a major cause of retinal detachment surgery failure. It is shrinkage or contraction of membrane over or under the surface of the retina. Retina is the light sensitive part that is responsible for conversion of light signals into the electric current that goes to the brain and enable us see things. Many approaches have been attempted to stop the development of PVR. Methotrexate infusion during pars plana vitrectomy has been tried. It has shown encouraging results in terms of prevention of development of PVR . Serial methotrexate intrasilicon oil injections are utilized. They also have showed promising results in terms of prevention of PVR.

Purpose of my research is to compare the efficacy of repeated intrasilicon oil Methotrexate injections with per operatively Methotrexate infusion in the prevention of Proliferative Vitreoretinopathy

Type of research intervention

The research participant will undergo surgical intervention. Participants will be divided into two groups. All participants will receive standard surgical treatment by Pars Plana Vitrectomy and silicon oil injection for the repair of rhegmatogenous retinal detachment. One groups will receive per operative methotrexate infusion while other group will receive repeated postoperative intrasilicon oil methotrexate injections.

Participant selection

For this research patients with rhegmatogenous retinal detachment are invited.

Voluntary participation

Patients' participation in this research is entirely voluntary. It is your choice whether to participate or not. In any case your treatment will not suffer. Your future follow up and management will not be affected.

Duration

After surgical intervention each patient will be followed up for three months.

Benefit

Results obtained would be used to find out the better regimen of methotrexate for the prevention of PVR. Thus, improving anatomical and functional outcome of the rhegmatogenous retinal detachment repair.

Confidentiality

The information that we collect from this research project will be kept confidential.

Sharing the results

The knowledge that will be gotten from doing this research will be shared with you through meetings before it is made widely available to the public. The results will be published in order that other interested people may learn from this research.

Right to refuse or withdraw

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all your rights will still be respected.

Who to contact

If you have any questions you may ask them now or later. If you wish to ask questions later, you may contact the following:

1) Dr. Ahmad Zeeshan Jamil

Professor of Ophthalmology. Sahiwal Teaching Hospital, Sahiwal, Pakistan.
Phone number: 03334853851
Email: ahmadzeeshandr@gmail.com

2) Muhammad Hannan Jamil
Assistant Professor of Ophthalmology, Ali Fatima Teaching Hospital Lahore, Pakistan
Phone number: 03336113166
Email: dr.m.hannan@gmail.com

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant/Patient_____

Signature of Participant/Patient_____

Date_____

I have accurately read out the information sheet to the potential participant/patient, and to the best of my ability made sure that the participant/patient understands that the following will be done:

1- All patients will undergo Pars Plana Vitrectomy for repair of rhegmatogenous retinal detachment. Patients will be divided into two groups.
2- One group will receive per operative methotrexate infusion while other group will receive repeated postoperative intrasilicon oil methotrexate injections.
3- Patients will be followed up for three months after surgical intervention

I confirm that the participant/patient was given an opportunity to ask questions about the study, and all the questions asked by the participant/patient have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant/patient.

Name of Researcher/person taking the consent_____

Signature of Researcher/person taking the consent_____

Date_____