Oral | Abstract 580

RETINAL DETACHMENT & PVR

RESULTS OF THE FIXER-MTC TRIAL

Short communication / Free Paper

Riemann C.*

Cincinnati Eye Institute ~ Cincinnati ~ United States of America

FIXER-MTX Trial investigates the efficacy and safety of intraoperative and postoperative Methotrexate (MTX) in reducing proliferative vitreoretinopathy (PVR) incidence following primary rhegmatogenous retinal detachment (RRD) repair. Design: FIXER-MTX (NCTNCT06541574) is a Phase 2b/3a randomized, double-masked, parallel-group, multi-center clinical trial conducted over a 12-month period. Participants: FIXER-MTX adult patients undergoing primary, acute RRD repair with a pars plana vitrectomy PPV repair. Patients with chronic RRD, previous RD repair with PPV or scleral buckle, presence of Grade C PVR, or contraindications to methotrexate use were excluded. Failed pneumatic retinopexy and Grade A and B PVR were included. Randomization began 3/2024 and has been ongoing.

Methods: Patients were randomized into 4 arms. 1) Intraoperative MTX infusion with 40mg MTX in the500mL BSS posterior segment infusate (MS group). 2) Postoperatively MTX with 400µg/0.05mL intravitreal injections at weeks one, three, six, and ten (SM group). 3) Both Intraoperative and postoperative MTX (MM) and 4) Control group given sham infusion and sham injections (SS). Patients completed 11 study visits over the span of 12 months. and Visual acuity (VA), intraocular pressure (IOP), ophthalmic examinations, PVR development, epiretinal membrane development and MTX-related side effects were recorded at each visit.

Results: Specific randomization N's, baseline characteristics, demographics and follow up will be described. MTX related complications will be described. Recurrent RD , Grade C PVR incidence, ERM incidence and Reoperations will be described.

Conclusions: The preplanned preliminary analysis of FIXER -MTX trial demonstrated an excellent safety profile for both intraoperative MTX infusions and postoperative MTX injections. Combined MTX infusion and injections seem to meaningfully reduce PVR more than MTX injections or infusions alone. These results justify continued recruitment of patients, expanding FIXER-MTX to additional sites and may justify protocol changes pending the analyses we will perform.