Comparative Study of OCT and OCT Angiography Biomarkers and Systemic Parameters in Diabetic Retinopathy After Three Loading Doses of Faricimab and Biosimilar Ranibizumab

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1. INTRODUCTION

Diabetic retinopathy (DR) and diabetic macular edema (DME) remain leading causes of vision impairment, with anti-VEGF therapy as the standard of care. Variability in treatment response highlights the need for early predictive biomarkers. Recent therapeutic advances include faricimab, a bispecific antibody targeting both VEGF-A and Ang-2 pathways, which has demonstrated promising anatomical and functional outcomes. In parallel, the increasing availability of biosimilar ranibizumab offers comparable efficacy and safety.

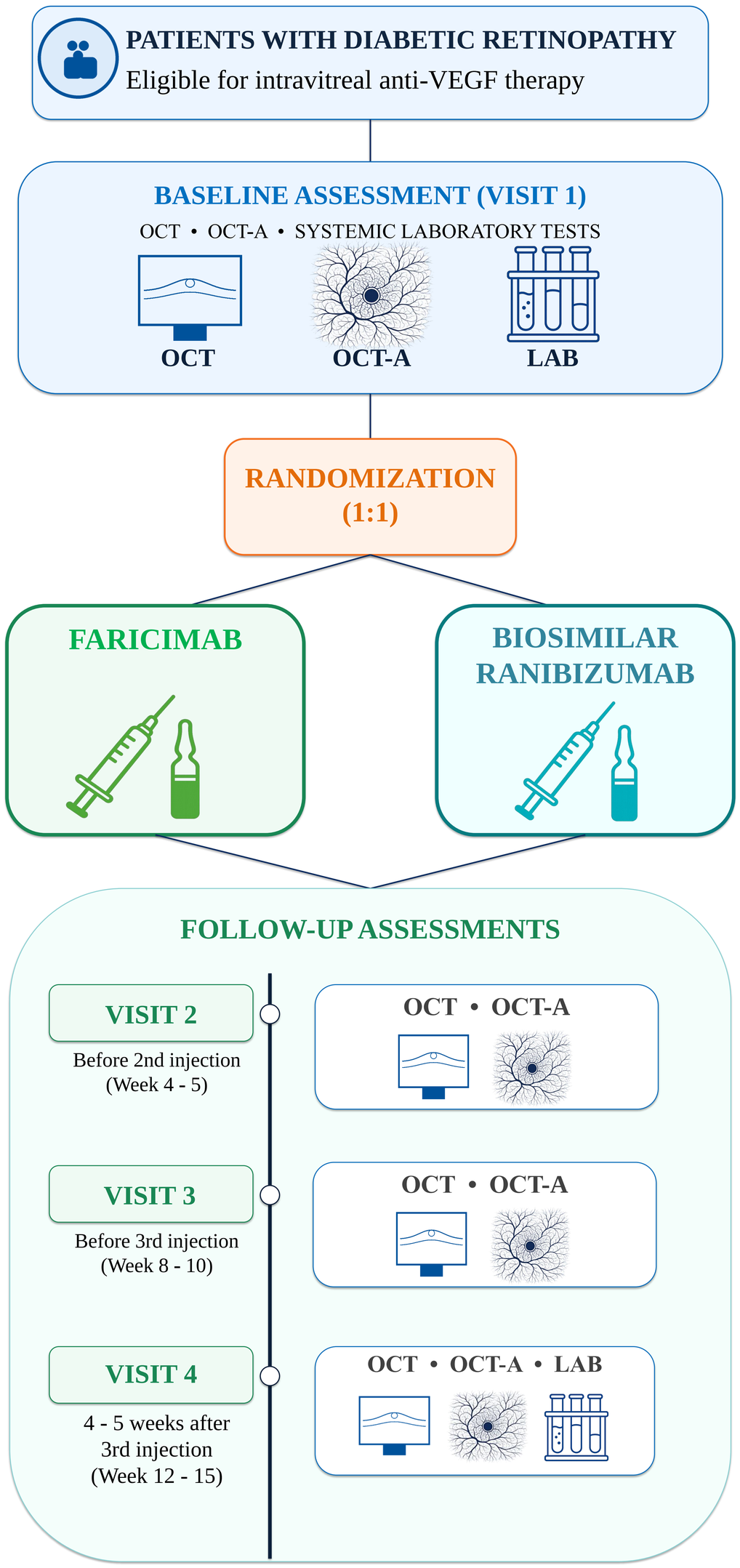
2. HYPOTHESIS

Specific OCT and OCT angiography (OCT-A) biomarkers are associated with early therapeutic response, with their predictive value differing between faricimab and biosimilar ranibizumab treatment.

3. AIMS

1. To identify OCT/OCT-A biomarkers associated with early response to faricimab vs biosimilar ranibizumab in DR.
2. To compare OCT/OCT-A biomarker changes after three loading doses between faricimab and biosimilar ranibizumab.
3. To assess the association between OCT/OCT-A biomarkers and systemic parameters in predicting early response.

STUDY DESIGN AND FLOW



DATA ANALYSIS

Comparison of anatomical and microvascular changes and their association with systemic parameters and early therapeutic response

EXPECTED OUTCOME AND IMPACT

Identification of predictive biomarkers for early response and optimization of personalized treatment in DR

4. MATERIALS / PARTICIPANTS AND METHODS

Study design

Prospective randomized study at the Department of Ophthalmology, University Hospital Osijek.

Participants

Patients with DR eligible for intravitreal anti-VEGF therapy.

Intervention

Randomized to faricimab or biosimilar ranibizumab, with injections every 4 – 5 weeks.

Assessments, OCT & OCT-A

Baseline, before 2nd and 3rd injections, and 4 – 5 weeks after the 3rd injection.

Laboratory tests

At baseline and final visit.

5. RESEARCH PLAN

- Patient recruitment and data collection
- Treatment administration and follow-up
- Data analysis
- Publication and dissemination

6. SIGNIFICANCE / EXPECTED SCIENTIFIC CONTRIBUTION

Direct comparative data on early anatomical and microvascular effects may improve treatment selection, optimize therapy, and support personalized DME management.

7. MeSH / KEYWORDS

Diabetic Retinopathy; Optical Coherence Tomography; Ranibizumab; Faricimab; Biomarkers