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Infographic: study design of the BALATON and COMINO phase 3 randomised trials of faricimab in patients with retinal vein occlusion

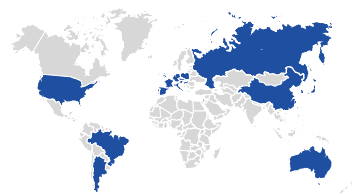
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Eye; <https://doi.org/10.1038/s41433-024-02936-2>

Study Design of the BALATON and COMINO Phase 3 Randomised Controlled Trials of Faricimab in Patients With Retinal Vein Occlusion

BALATON and COMINO were nearly identical, active comparator-controlled, global, phase 3 studies conducted across 22 countries



BALATON 553 patients, 149 centres BRVO	COMINO 729 patients, 153 centres CRVO or HRVO
Age ≥18 years	
Treatment-naïve macular oedema due to RVO diagnosed ≤4 months before screening	
Study eye: BCVA 19–73 letters, CST ≥325 μm*	
✗ Any other ocular condition that could contribute to irreversible vision loss	
PRP treatment or cataract surgery ≤3 months before day 1	
Any prior intraocular surgery	
Prior macular laser treatment	



BALATON and COMINO are designed to evaluate the efficacy, safety and pharmacokinetics of faricimab in RVO



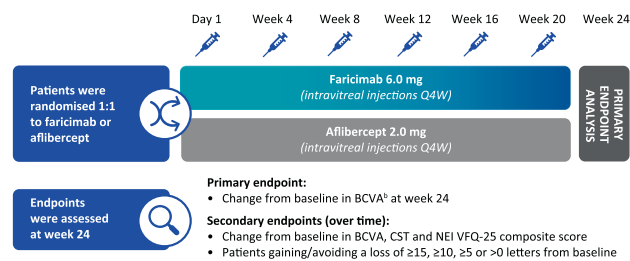
Faricimab targets VEGF-A and Ang-2, both of which play an underlying role in retinal vascular disease progression



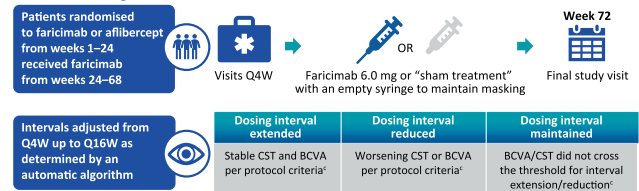
BALATON and COMINO are the first pivotal trials to evaluate a modified T&E-based treatment regimen to manage RVO

BALATON and COMINO will provide key insights on the efficacy and safety of faricimab in patients with macular oedema due to RVO and on the benefits of a modified T&E-based dosing regimen in reducing treatment burden

Day 1–Week 24 (double-masked): evaluation of efficacy of faricimab vs aflibercept



Weeks 24–72 (treatment interval masked): evaluation of faricimab durability using modified T&E-based dosing



- Secondary endpoints (weeks 24–72):**
- Proportion of patients on a Q4W, Q8W, Q12W or Q16W treatment interval at week 68
 - Change from baseline in BCVA, CST and NEI VFQ-25 composite score over time
 - Proportion of patients gaining/avoiding a loss of ≥15, ≥10, ≥5 or >0 letters from baseline over time

¹ Hattenbach L, et al. BALATON and COMINO: Phase III randomized clinical trials of faricimab for retinal vein occlusion: study design and rationale. *Ophthalmol Sci*. 2023;3:100302. ^a CST ≥325 μm (Spectralis SD-OCT) or ≥315 μm (Cirrus SD-OCT or Topcon SD-OCT) at screening. ^b Measured using the ETDRS visual acuity chart at a starting distance of 4 m. ^c Please see reference 1 for details of specific BCVA/CST criteria and for specific rules regarding interval extension if dosing was reduced. Ang-2: angiopoietin-2, BCVA: best-corrected visual acuity, BRVO: branch retinal vein occlusion, CRVO: central retinal vein occlusion, CST: central subfield thickness, ETDRS: Early Treatment Diabetic Retinopathy Study, HRVO: hemi retinal vein occlusion, NEI VFQ-25: National Eye Institute Visual Function Questionnaire-25, PRP: panretinal photocoagulation laser, Q4W/Q8W/Q12W/Q16W: every 4/8/12/16 weeks, RVO: retinal vein occlusion, SD-OCT: spectral domain optical coherence tomography, T&E: treat-and-extend, VEGF-A: vascular endothelial growth factor-A.

Fig. 1 This infographic summarises the design of two nearly identical phase 3 trials of faricimab, a dual angiopoietin-2/vascular endothelial growth factor-A inhibitor, in patients with macular edema due to retinal vein occlusion: BALATON (NCT04740905) and COMINO (NCT04740931). Patients were randomised to receive faricimab 6.0 mg or aflibercept 2.0 mg monthly from day 1 to week 24 to compare the efficacy of faricimab versus aflibercept. The primary endpoint at week 24 was the mean change from baseline in best-corrected visual acuity. From weeks 24 to 72, all patients received faricimab 6.0 mg according to a modified treat-and-extend based regimen, with dosing up to every 16-weeks to evaluate treatment durability.

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COMPETING INTERESTS

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ADDITIONAL INFORMATION

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