Protocol 22001 for A Randomized, Active-Controlled, Open-Label Study to Evaluate the Clinical Performance of Deseyne (vifilcon C) Daily Disposable Soft Contact Lens

26APR2023

TITLE PAGE

A Randomized, Active-Controlled, Open-Label Study to Evaluate the Clinical Performance of Deseyne (vifilcon C) Daily Disposable Soft Contact Lens

PROTOCOL 22001

Sponsor: Bruno Vision Care

This clinical investigation is being conducted in accordance with 21 Code of Federal Regulations (CFR) Parts 11, 50, 54, 56, and 812. The protocol was developed with consideration of the provisions in: International Organization for Standardization (ISO) 14155-1:2011 Clinical investigation of medical devices for human subjects – Part 1: General requirements; 14155-2:2011 Part 2: Clinical investigation of medical devices for human subjects – Part 2: Clinical investigational plan; ISO 11980:2012 Ophthalmic Optics – Contact lenses and contact lens care products – Guidance for clinical investigations; International Council for Harmonisation (ICH) Good Clinical Practice (GCP) and applicable local regulations. The Sponsor intends to register this clinical trial with the public database https://ClinicalTrials.gov.

Revision Chronology:

Original	2.0	13 February 2023
Amendment	3.0	26 April 2023

SPONSOR APPROVAL PAGE

A Randomized, Active-Controlled, Open-Label Study to Evaluate the Clinical Performance of Deseyne (vifilcon C) Daily Disposable Soft Contact Lens

PROTOCOL 22001

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INVESTIGATOR STATEMENT OF APPROVAL

A Randomized, Active-Controlled, Open-Label Study to Evaluate the Clinical Performance of Deseyne (vifilcon C) Daily Disposable Soft Contact Lens

PROTOCOL 22001

I have read the attached document, concur that it contains all information necessary to conduct the study, and agree to abide by all provisions set forth therein.

I agree to conduct this study in accordance with 21 Code of Federal Regulations (CFR) Parts 11, 50, 54, 56, and 812. The protocol was developed with consideration of the provisions in: International Organization for Standardization (ISO) 14155-1:2011 Clinical investigation of medical devices for human subjects – Part 1: General requirements; 14155-2:2011 Part 2: Clinical investigation of medical devices for human subjects – Part 2: Clinical investigational plan; ISO 11980:2012 Ophthalmic Optics – Contact lenses and contact lens care products – Guidance for clinical investigations, International Council for Harmonisation (ICH) Good Clinical Practice (GCP) and applicable local regulations.. I will not initiate the study until I have obtained written approval by the appropriate Institutional Review Board (IRB)/Ethics Committee and have complied with all financial and administrative requirements of the governing body of the clinical institution and the Sponsor. I will obtain written informed consent from each study subject prior to performing any study specific procedures.

I understand that my signature on a case report form indicates that the data therein has been reviewed and accepted by me.

I understand that this document and related information is subject to confidentiality terms found in my signed Confidentiality or Clinical Services Agreement. I agree to protect the confidentiality of my patients when allowing the Sponsor of this clinical investigation, and/or relevant regulatory authorities and IRB/ECs, direct access to my medical records for study subjects.

_____

Principal Investigator, Printed Name

_____ _____

Principal Investigator, Signature Date

1. SYNOPSIS

Title:	A Randomized, Active-Controlled, Open-Label Study to Evaluate the Clinical Performance of Deseyne (vifilcon C) Daily Disposable Soft Contact Lens
Sponsor:	Bruno Vision Care
Phase of study:	Safety and effectiveness
Study number:	22001
Number of study centers and subjects:	Approximately 80 subjects (160 eyes) will be treated at approximately 4 to 5 investigational (non-institutional) sites in the United States.
Objective:	The objective of this clinical study is to provide clinical performance data comparing the test lens (Deseyne [vifilcon C] daily disposable soft contact lens) to a control lens (1-Day Acuvue® Moist® [etafilcon A] daily disposable soft contact lens) in the same indication for use (single use prior to removal followed by a fresh lens upon the next lens wear exposure).
Study design:	A multicenter, randomized, active-controlled, open-label study design will be used to compare the clinical performance of the Deseyne (vifilcon C) test soft contact lens to the similarly indicated 1-Day Acuvue Moist (etafilcon A) control soft contact lens. Study participation is approximately 90 days in duration and will consist of approximately 80 subjects assigned in a 2:1 ratio to test or control lens bilaterally, respectively. Subjects must be otherwise healthy, with myopia between -1.00 diopter (D) and -6.00 D and astigmatism no greater than 1.00 D that does not interfere with visual acuity (VA). At the Screening Visit, approximately two-thirds of the eligible subjects will be randomized to receive the test lens (Deseyne [vifilcon C] lens) and the other one-third eligible subjects will be randomized to receive the control lens (1-Day Acuvue Moist [etafilcon A] lens). At the Dispensing Visit (Visit 2), subjects will be provided with test or control lenses as part of the dispensing package, along with instructions for the use and care of the lenses. They will be recommended unpreserved lubricating/rewetting solution for use as needed during the study. Subjects will wear their assigned lenses bilaterally on a daily wear basis, for a minimum of 6 hours/day throughout the study (no maximum time is mandated, as long as subjects do not sleep in their lenses), with additional visits planned for 1 Week (Visit 3), 1 Month

	(Visit 4), 2 Months (Visit 5), and 3 Months/Exit Visit (Visit 6).
Subject selection:	*Inclusion criteria:* 1. 18 to 40 years of age on the date the informed consent form (ICF) is signed 2. Presence of clear central corneas and absence of any anterior segment disorders in each eye 3. Presence of myopia and requirement for lens correction from -1.00 D to -6.00 D in each eye 4. Best-corrected distance visual acuity (BCDVA) of 50 Early Treatment Diabetic Retinopathy Study letters (0.1 logMAR) or better in each eye 5. Be an adapted soft contact lens wearer in each eye and agreement to wear study lenses in each eye on a daily wear basis and not wear a non-study lens for approximately 3 months 6. Able and willing to comply with all treatment and follow-up/study procedures 7. Able to read, understand, and provide written informed consent on the Institutional Review Board−approved ICF and provide authorization as appropriate for local privacy regulations *Exclusion criteria:* 1. Participation in any drug or device clinical investigation within 2 weeks prior to Screening and/or during the period of study participation 2. Women of childbearing potential (those who are not surgically sterilized or postmenopausal) who meet any of the following conditions: a. Currently pregnant b. Plans to become pregnant during the study c. Currently breastfeeding 3. History of gas permeable lens wear in either eye within 30 days prior to Screening or history of polymethylmethacrylate lens wear in either eye within 3 months prior to Screening 4. Current monovision, multifocal, or toric contact lens wear in

	either eye 5. In either eye, current nonabsorbable punctal plug or implantation of absorbable punctal plug within 2 to 6 months (depending on type of absorbable plug) prior to Screening, or punctal plug removal within 2 months prior to Screening. Permanent punctal occlusion in 1 or more puncta or nasolacrimal duct obstruction in either eye is excluded 6. Use of any prescription ocular medication throughout the duration of the study. Prescription eyedrops for dry eye disease (eg, Restasis, Xiidra, Cequa, Eysuvis), as well as nasally administered Tyrvaya, must be discontinued 2 weeks prior to Screening and are prohibited throughout the duration of the study 7. Use of over-the-counter eyedrops (eg, oxymetazoline, naphazoline, ketotifen, etc.), except for unpreserved lubricant eyedrops or artificial tears (eg, Systane, Refresh), within 1 week prior to Screening and throughout the duration of the study 8. Use of any systemic or topical medications that may, in the Investigator's opinion, affect ocular physiology or lens performance 9. Anisometropia (spherical equivalent) >2.00 D 10. Ocular astigmatism >1.00 D in either eye 11. Amblyopia in either eye 12. Aphakia in either eye 13. Active ocular disease (eg, dry eye disease, blepharitis, conjunctivitis, keratitis, etc.) in either eye. Subjects must be symptom free for at least 7 days 14. History or evidence of ocular infection within 30 days prior to Screening 15. History or evidence of ocular herpes simplex or ocular herpes zoster 16. Any grade corneal infiltrates in either eye 17. Grade ≥2 finding in either eye during slit lamp examination 18. Any "Present" finding in either eye during slit lamp examination that, in the Investigator's opinion, may interfere with contact lens wear 19. Any scar or neovascularization within the central 4 mm of the cornea in either eye. Subjects with minor peripheral corneal scarring (not extending into the central area) that, in the Investigator's opinion, does not interfere with contact lens wear are eligible to participate in this study

	20. History of any corneal surgery (eg, refractive surgery or therapeutic) in either eye 21. Any systemic disease currently affecting ocular health or which, in the Investigator's opinion, may have an effect on ocular health in either eye during the course of the study 22. Allergy to any component in the study care products 23. Meet any of the following criteria: a. Subject is an employee of the investigative site b. Subject or a member of the subject's household is an ophthalmologist, an optometrist, an optician, or an ophthalmic assistant/technician c. Subject or a member of the subject's household is an employee of a manufacturer of contact lenses or contact lens care products d. Subject or a member of the subject's household is an employee of a market research firm
Planned study period and duration of treatment:	The duration of lens wear (and duration of study participation) will be approximately 90 days.
Test lens:	The Deseyne (vifilcon C) investigational spherical soft hydrophilic lens is proposed to be indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic and/or aphakic persons with non-diseased eyes with up to and including 1.00 D of astigmatism that does not interfere with VA. • Sphere power: -12.00 to +7.00 D • Diameter: 14.1 mm • Base curve: 8.6 mm • Material: vifilcon C
Control lens:	1-Day Acuvue Moist (etafilcon A) daily disposable soft contact lens (Vistakon): • Sphere power: -9.00 to +6.00 D • Diameter: 14.2 mm • Base curve: 8.5, 9.0 mm • Material: etafilcon A

<table>
<tr><td>Schedule of study visits:</td><td>
<table>
<tr><th>Visit Number</th><th>Visit Name</th><th>Target</th><th>Acceptable Visit Range</th></tr>
<tr><td>1</td><td>Screening Visit</td><td>None</td><td>Day -30 to -7</td></tr>
<tr><td>2</td><td>Dispensing Visit</td><td>Day 1</td><td>Not applicable</td></tr>
<tr><td>3</td><td>1-Week Visit</td><td>Day 8</td><td>Day 5−9</td></tr>
<tr><td>4</td><td>1-Month Visit</td><td>Day 31</td><td>Day 27−35</td></tr>
<tr><td>5</td><td>2-Month Visit</td><td>Day 61</td><td>Day 54−68</td></tr>
<tr><td>6</td><td>3-Month/Exit Visit</td><td>Day 92</td><td>Day 91−101</td></tr>
</table>
</td></tr>
<tr><td>Primary effectiveness endpoints:</td><td>There will be 2 primary effectiveness endpoints for the study:
Change from baseline to each post-baseline visit in distance logMAR VA by eye
Number and percentage of subjects, where there is no more than a 5−logMAR letters read loss from baseline (change from baseline in number of letters read ≥ -5). This is calculated by eye at each post-baseline visit.</td></tr>
<tr><td>Secondary effectiveness endpoints:</td><td>Secondary effectiveness endpoints will include distance VA; symptoms/complaints and subjective assessments; lens wettability, centration, and movement; and lens deposits at each post-baseline visit and the satisfaction survey (modified Visual Functioning Questionnaire) at the Screening and Exit Visits.</td></tr>
<tr><td>Safety endpoints:</td><td>The primary safety endpoint will be the proportion of eyes with any slit lamp findings (including corneal edema [epithelial, stromal], corneal infiltrates, corneal vascularization, corneal staining, palpebral conjunctival injection, and limbal injection) Grade >2 at any follow-up visit between the test and control lenses.
Secondary safety endpoints will include adverse reactions (serious and incidental), adverse device effects, pinhole VA (for eyes with a 2-line decrease in BCDVA or worse from baseline), conjunctival hyperemia as measured by the Cornea and Contact Lens Research Unit grading scale, keratometry, slit lamp biomicroscopy, spherocylindrical refraction, BCDVA, corneal fluorescein staining, lens discontinuation rates at any follow-up visit, and use of unpreserved lubricant eyedrops or artificial tears during the study.</td></tr>
<tr><td>Statistics:</td><td>All analyses will be descriptive in nature. A full declaration of planned statistical analyses will be documented in a formal Statistical Analysis Plan.</td></tr>
<tr><td>Sample size:</td><td>The sample size of approximately 80 subjects (160 eyes) is considered sufficient for evaluation of the clinical performance of the test and control lenses. The sample size was not based on statistical power considerations. A dropout rate of approximately 20% is expected;</td></tr>
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	thus, approximately 60 subjects (120 eyes) are targeted to be described in this study.