Blue Ocean Clinical Research East -Current Studies-The Villages

Surface C-100-001

A Research Study To See How Well an Eye Drop, SURF-100 (A Mycophenolic Acid/Betamethasone Sodium Phosphate Combination), Works and What Side Effects There Are in Subjects With Dry Eye Disease

Sponsor:
Surface Pharmaceuticals, Inc.
Information provided by (Responsible Party):
Surface Pharmaceuticals, Inc.

Study Description

Brief Summary:

SURF-100 is being studied for the treatment of dry eye disease. SURF-100 is an investigational drug (which means the study drug is currently being tested) in the form of a sterile eye drop.

The purpose of this research study is to see how well SURF-100 works to treat dry eye and what potential side effects there are, and to compare it with Vehicle (placebo), 0.1% mycophenolic acid (MPA) in Vehicle, 0.3% MPA in Vehicle, 0.01% betamethasone phosphate (BSP) in Vehicle, Restasis and Xiidra. This study will involve about 280-350 study participants age 18 and older at about 40 different research sites in the United States.

Condition or disease	Intervention/treatment	Phase
Dry Eye Disease	Drug: Combination of 0.3% Mycophenolic Acid and 0.01% Betamethasone Sodium PhosphateDrug: PlaceboDrug: Mycophenolic Acid 0.1%Drug: Restasis 0.05% Ophthalmic EmulsionDrug: Xiidra 5% Ophthalmic SolutionDrug: Mycophenolic Acid 0.3%Drug: Betamethasone Sodium Phosphate 0.01%	Phase 2

Study Design

Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	280 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose:	Treatment

Official Title: A Multicenter, Randomized, Double-Masked Study To Evaluate The Safety, Tolerability, And Efficacy Of SURF-100 Ophthalmic Solution (A Mycophenolic Acid/Betamethasone Sodium Phosphate Combination) In Subjects With Dry Eye Disease

Actual Study Start Date: January 11, 2021
Estimated Primary Completion Date: December 2021
Estimated Study Completion Date: January 2022

Arms and Interventions

Arm	Intervention/treatment
Experimental: SURF-100 (a combination of 0.3% MPA and 0.01% BSP) One drop in the study eye twice daily (BID) for 84 days	Drug: Combination of 0.3% Mycophenolic Acid and 0.01% Betamethasone Sodium Phosphate combination of a topical immunosuppressant and a topical corticosteroid solution
Experimental: 0.1% MPA One drop in the study eye BID for 84 days.	Drug: Mycophenolic Acid 0.1% topical immunosuppressant
Experimental: 0.3% MPA One drop in the study eye BID for 84 days.	Drug: Mycophenolic Acid 0.3% topical immunosuppressant
Experimental: 0.01% BSP One drop in the study eye BID for 84 days.	Drug: Betamethasone Sodium Phosphate 0.01% topical corticosteroid solution
Placebo Comparator: Vehicle One drop in the study eye BID for 84 days.	Drug: Placebo topical vehicle solution
Active Comparator: Restasis One drop in the study eye BID for 84 days	Drug: Restasis 0.05% Ophthalmic Emulsion topical ophthalmic emulsion
Active Comparator: Xiidra One drop in the study eye BID for 84 days	Drug: Xiidra 5% Ophthalmic Solution topical ophthalmic solution

Outcome Measures

Primary Outcome Measures :
UNC DEMS Score [Time Frame: Day 84]
A reduction of 10% in patient-reported dry eye disease symptoms and reduction of impact of symptoms on daily life as defined by the University of North Carolina (UNC) Dry Eye Management Scale (DEMS) with SURF-100 as compared to vehicle, RESTASIS and XIIDRA.

Secondary Outcome Measures :
Tear Break Up Time (TBUT) [Time Frame: Day 84]
Average increase in TBUT compared to vehicle, RESTASIS and XIIDRA

Schirmer Tear Test Score [Time Frame: Day 84]
Average increase in Schirmer's score test (with anesthesia) compared to vehicle, RESTASIS and XIIDRA.

Eligibility Criteria

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

1. Adults at least 18 years of age at the time of the Screening visit.
2. Willing and able to read, sign, and date the informed consent form (ICF) after the nature of the study has been explained and any questions have been answered, and prior to initiation of any study procedures or exams.
3. Willing and able to comply with all study procedures and attend all study visits.
4. Willing to suspend use of tear substitutes at least 72 hours prior to Visit 2 (Day 0) through Visit 7 (Day 98).
5. Best corrected visual acuity (BCVA) of 0.7 log of the minimum angle of resolution (logMAR) or better (Snellen equivalent score of 20/100 or better) in each eye at Visit 1 (Day -14 to Day 0).

6. Subject-reported history of dry eye in both eyes.
7. Meeting ALL of the following criteria in the same eye at Visit 1 (Day -14 to Day 0) and meeting ALL of the following criteria in the same eye at Visit 2 (Day 0) if Visit 2 is performed >5 days after Visit 1:
    a. Minimum score of greater than or equal to 5 but less than or equal to 9 on UNC DEMS questionnaire.
    b. Schirmer Tear Test (with anesthesia) equal to or less than 10 mm, but more than 1 mm.
    c. TBUT: Equal to or less than 5 seconds
8. A negative urine pregnancy test if female and of childbearing potential (those who are not surgically sterilized [bilateral tubal ligation, hysterectomy, or bilateral oophorectomy] or post-menopausal [12 months after last menses] or premenarchal) and must have used adequate birth control throughout the study period (through Visit 7 [Day 98]). Adequate birth control is defined as hormonal-oral, implantable, injectable, or transdermal contraceptives; mechanical - spermicide in conjunction with a barrier such as condom or diaphragm; intrauterine device; abstinence; or surgical sterilization of male partner.
9. Subjects with secondary Sjögren's syndrome (e.g., rheumatoid arthritis, systemic lupus erythematosus) or other autoimmune diseases (e.g., multiple sclerosis, inflammatory bowel disease) are eligible for study consideration provided the subject meets all other inclusion and exclusion criteria, AND are not in a medical state - in the opinion of the principal investigator - that could interfere with study parameters, are not taking systemic/ocular steroids, and are not immunodeficient/immunosuppressed (e.g., receiving systemic immunomodulating or immunosuppressive drugs to manage their baseline medical state).

Exclusion Criteria:

1. Contraindications or known hypersensitivity to the study drug(s), including RESTASIS or XIIDRA, or their components.
2. Subjects who are employees or immediate family members of employees at the investigational site.
3. Subjects who are members of the same household.
4. Any ocular condition that, in the opinion of the investigator, may affect study parameters including, but not limited to, lid margin disorders (e.g., blepharitis including staphylococcal, demodex, or seborrheic; excessive lid laxity, floppy eyelid syndrome, ectropion, entropion), advanced conjunctivochalasis, Salzmann's nodular degeneration, and asthenopia-related conditions, allergic conjunctivitis, glaucoma, diabetic retinopathy, follicular conjunctivitis, iritis, uveitis, wet-exudative age-related macular degeneration, retinal vein occlusion, and/or active ocular inflammation.
5. Any condition that could affect trigeminal nerve function including facial or ocular Herpes Zoster/Shingle, a stroke or nerve palsy affecting the eye(s).

6. Use of any topical medication and/or antibiotics for the treatment of blepharitis or meibomian gland disease in either eye within 14 days prior to Visit 2 (Day 0).
7. Active or history of ocular herpes or any other ocular infection in either eye within the last 30 days prior to Visit 1 (Day -14 to Day 0).
8. Unwilling to avoid wearing contact lenses for 7 days prior to Randomization (Visit 2, Day 0) and for the duration of the study period (through Visit 7, Day 98).
9. Positive urine pregnancy test at Screening, nursing an infant or planning to become pregnant during the study.
10. Any blood donation or significant loss of blood within 56 days of Visit 1 (Day -14 to Day 0).
11. Any history of immunodeficiency disorder, human immunodeficiency virus (HIV), positive hepatitis B, C, or evidence of acute active hepatitis A (anti-hepatitis A virus immunoglobulin M), or organ or bone marrow transplant.
12. Any medication (oral or topical) known to cause ocular drying that is not administered as a stable dose for at least 30 days prior to Visit 1 (Day -14 to Day 0) and for the duration of the study (Visit 7, Day 98); antihistamines are not allowed at any time during the study.
13. Use of prohibited medications (topical, topical ophthalmic and/or systemic, during the appropriate pre-study washout period (see below) and during the study. Prohibited medications include topical cyclosporine or lifitegrast, use of any other ophthalmic medication (e.g., glaucoma medication, topical anti-inflammatory eye drops) for the duration of the study)

    NOTE: Supplements containing omega-3 are allowed if the subject has been taking said supplement for at least 3 months prior to Screening. Subjects are not allowed to begin taking supplements containing omega-3 during the study. The appropriate pre-study washout period is as follows:

    a. Antihistamines (including ocular): 7 days prior to Visit 1 (Day -14 to Day 0).
    b. Topical cyclosporine or lifitegrast or omega-3s within 14 days prior to Visit 1 (Day -14 to Day 0).
    c. Corticosteroids or mast cell stabilizers (including ocular): 14 days prior to Visit 1 (Day -14 to Day 0).
    d. Depot-corticosteroids in either eye at least 45 days prior to the first dose of study drug (Day 0)
    e. All other topical ophthalmic preparations (including artificial tear substitutes other than the study drops): 72 hours prior to Visit 1 (Day -14 to Day 0).
    f. Introduction of any new, nonsteroidal anti-inflammatory drugs (NSAIDs) including but not limited to topical, systemic (including sleep-aids containing NSAIDs), inhaled, or irrigation solution within 7 days prior to the first dose of study drug. Subjects who are on stable dose of NSAIDs (stable for at least 4 weeks prior to the first dose of study drug) are eligible for participation and

should remain on a stable dose throughout the duration of the study (i.e., through Day 98).

g. Triamcinolone in either eye at least 90 days prior to the first dose of study drug (Day 0).

h. Inhaled, ingested, sublingual, transdermal or topical products containing marijuana, tetrahydrocannabinol (THC) or cannabidiol (CBD) at least 7 days prior to the first dose of study drug (Day 0).

i. Systemic pain relievers, analgesics (e.g., pregabalin, gabapentin, opioids) 14 days prior to the first dose of study drug (Day 0).

j. Any supplement, prescribed medication or over-the-counter product that the investigator feels may interfere with the study parameters, including homeopathic remedies, analgesics, and pain medication.

k. Oral doxycycline within 6 months of first dose of study drug (Day 0).

l. Diuretics: Within 28 days prior to Visit 1 (Day -14 to Day -1).

m. Punctal occlusion:

i. Punctal cauterization: Randomization may not occur until 4 weeks following the procedure.

ii. Permanent/semi-permanent punctal plugs (this includes 180-day punctal plugs): Randomization may not occur until 4 weeks following the procedure. If a punctal plug falls out during the study, it should be reinserted.

iii. Temporary collagen punctal plugs: Not permitted. If subject has a history of use of temporary punctal plugs, randomization may not occur until 4 weeks since last insertion and puncta are plug-free, as determined by the investigator.

14. Any significant chronic illness that, in the opinion of the investigator, could interfere with the study parameters, including, but not limited to, severe cardiopulmonary disease, poorly controlled hypertension, and/or poorly controlled diabetes.
15. Use of any investigational product or device within 30 days prior to Visit 1 (Day -14 to Day 0) or during the study period.
16. History of LASIK or similar type of corneal refractive surgery within 12 months prior to Visit 1 (Day -14 to Day 0), and/or any other ocular surgical procedure within 12 months prior to Visit 1 (Day -14 to Day 0); or any scheduled ocular surgical procedure during the study period.
17. Use of any laser procedure for the eyes in the 30 days prior to Visit 1 (Day -14 to Day 0).
18. Known history of alcohol and/or drug abuse within the past 12 months that in the opinion of the principal investigator, may interfere with study compliance, outcome measures including safety parameters, and/or the general medical condition of the subject.

19. Subjects with dry eye secondary to scarring (such as that seen with irradiation, alkali burns, Stevens Johnson syndrome, cicatricial pemphigoid) or destruction of conjunctival goblet cells (as with vitamin A deficiency) are not eligible for the study. Subjects with incidental scars secondary to refractory surgery (i.e., LASIK surgery) that, in the opinion of the principal investigator, would not interfere with study compliance and/or outcome measures, are not excluded from the study.
20. Subjects who test positive for the COVID-19 virus within 30 days prior to Visit 1 (Day -14 to Day 0).