Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Active Post Marketing Surveillance to Evaluate the Efficacy and Safety of bFGF in Combination with NBUVB for the Treatment of Vitiligo; A Triple-blind, Randomized, Placebo-controlled Clinical Trial

Protocol summary

Study aim

Evaluating the efficacy and safety of bFGF in combination with NBUVB for the treatment vitiligo

Design

This study will be performed as an active post marketing surveillance phase 4, triple-blind (patient, physician and outcome assessor), placebo-controlled study with a superiority approach to evaluate the efficacy and safety of bFGF peptide serum in the treatment of vitiligo patches on the face.

Settings and conduct

Razi Hospital, Tehran, Iran

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male or females aged 18 to 65, signed the informed consent form, Diagnosis of non-segmental vitiligo not more than 5 years, Stable vitiligo for at least 6 months, Candidate for phototherapy, Have not been receiving any topical or systemic treatments for vitiligo for the past 6 weeks, Have not been receiving phototherapy during the past 6 months, Not having any physical or mental conditions that would interfere with the patient’s participation in the study or endanger their safety in the opinion of the investigator, Patients with general good health (except vitiligo) as judged by the Investigator Exclusion criteria: Women of childbearing potential, or breastfeeding, Diagnosis of extensive or unstable vitiligo, Patients with skin cancer or precancerous skin lesions, Patients with poliosis in > 50% of their vitiligo patches, Patients with complete facial depigmentation, Diagnosis of segmental or mixed vitiligo, Subjects whose vitiligo has not responded to phototherapy or patients who have received phototherapy in the past 6 months, Patients with contraindication to NBUVB, Patients with known allergy to the product's excipients

Intervention groups

One group receives bFGF peptide serum and the other will only receive vehicles (both will be treated with NBUVB during the study)

Main outcome variables

Percentage of repigmentation by comparing photos taken from facial lesions

General information

Reason for update

Change in the study title (after ethics committee approval)

Acronym

IRCT registration information

IRCT registration number: **IRCT20201104049265N1**
Registration date: **2021-07-08, 1400/04/17**
Registration timing: **prospective**

Last update: **2021-10-12, 1400/07/20**
Update count: **1**

Registration date

2021-07-08, 1400/04/17

Registrant information

Name
Seyyedeh Maryam Afshani

Name of organization / entity
Arta Zist Pharmed

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-10, 1400/04/19

Expected recruitment end date

2021-09-11, 1400/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Active Post Marketing Surveillance to Evaluate the Efficacy and Safety of bFGF in Combination with NBUVB for the Treatment of Vitiligo; A Triple-blind, Randomized, Placebo-controlled Clinical Trial

Public title

Phase IV Clinical Trial to Evaluate the Efficacy and Safety of basic Fibroblast Growth Factor Compared to Placebo in Combination with NBUVB for the Treatment of Vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

- Male or female patients aged 18 to 65 years - Willingly signed the written informed consent form - Diagnosis of non-segmental vitiligo no longer than 5 years with symmetrical lesions except for the eyelids - Stable vitiligo for at least 6 months (no new patches, or less than 10% increase in the diameter of the existing patches for at least 6 months - Candidate for phototherapy (more than 25% body surface involvement) - Have not been receiving any topical or systemic treatments for vitiligo for the past 6 weeks - Have not been receiving phototherapy during the past 6 months - Not having any physical or mental conditions that would interfere with the patient’s participation in the study or endanger their safety in the opinion of the investigator - Patients with general good health (except vitiligo) as judged by the Investigator

Exclusion criteria:

- Women of childbearing potential, or breastfeeding women - Diagnosis of extensive or unstable vitiligo - Patients with skin cancer or precancerous skin lesions - Patients with poliosis in > 50% of their vitiligo patches - Patients with complete facial depigmentation - Diagnosis of segmental or mixed vitiligo - Subjects whose vitiligo has not responded to phototherapy or patients who have received phototherapy in the past 6 months - Patients with contraindication to NBUVB (pemphigus, Systemic Lupus Erythematosus, cataract, Xeroderma pigmentosum, patients receiving immunosuppressants due to organ transplantation, excessive photosensitivity) - Patients with known allergy to the product's ingredients and excipients (isopropyl alcohol, propylene glycol, isopropyl myristate, and phenoxy ethanol)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into 2 groups. Both groups will be treated equally with phototherapy (NBUVB), the intervention group will administer bFGF serum and the control group will administer the vehicle. Roller bottles are not different in appearance; Therefore, patients will not be able to distinguish the bFGF-containing roller from the vehicle. Sealedenvelope.com and has been used to create a list of random codes with block sizes of four.

Blinding (investigator's opinion)

Triple blinded

Blinding description

As the serum containing bFGF and the vehicle are completely alike in their appearance, and the method and timing of administration are the same, it is expected that both the patient and the physician are unaware of receiving bFGF or vehicle. In this study, in addition to the physician and the patients, the outcome assessor will also be blind to the assigned interventions, and therefore the study will be performed as a triple-blind phase IV clinical trial.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Vahdat Eslami Square, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1199663911

Approval date

2021-07-03, 1400/04/12

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.412

Health conditions studied

1

Description of health condition studied
Vitiligo
ICD-10 code
L80
ICD-10 code description
Vitiligo

Primary outcomes

1

Description
Percentage of repigmentation
Timepoint
Baseline, week 6, and week 16
Method of measurement
Comparison of photos taken from lesions

Secondary outcomes

1

Description
Patients' satisfaction score
Timepoint
Baseline, week 6, and week 16
Method of measurement
Asking the patient to rate their satisfaction from a scale of 0 to 10 points

2

Description
Occurrence of any adverse reactions or adverse events
Timepoint
Throughout the study period
Method of measurement
Dairy card distribution

Intervention groups

1

Description
Intervention group: BFGF serum that is administered topically to the lesions every night and the patient will be exposed to sunlight for 5 to 10 minutes the next day between 11 AM and 15 PM.
Category
Treatment - Drugs

2

Description
Control group: Vehicle (placebo) that is administered topically on the lesions every night and the patient will be exposed to sunlight for 5 to 10 minutes the next day between 11 AM and 15 PM.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Dr. Amir Houshang Ehsani
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Imen Vaccine Alborz
Full name of responsible person
Dr. Setayesh Sadeghi
Street address
Alborz, Nazarabad, Sepehr Industrial Town, West Bahman St., No. 110
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Nazarabad
Province
Alborz
Postal code
1399114913
Phone
+98 26 4533 4189
Email
info@imenvaccine.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Imen Vaccine Alborz
Proportion provided by this source
100
Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Arta Zist Pharmed

Full name of responsible person

Dr. Setayesh Sadeghi

Position

Medical department Manager

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Full name of responsible person

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Person responsible for updating data

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Position

Medical department supervisor

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available