A clinical study of MK-6194 for the treatment of vitiligo (MK-6194-007)

Estado	Tipo de Participantes	Rangos de Edad
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	134
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Tiene resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica, farmacogenética, farmacoeconómica	NO

Información

Identificador
2023-503502-37-00 (CTIS)

Cod. Protocolo
MK-6194-007

Área terapéutica
Enfermedades [C] - Patologías del sistema inmunitario [C20]|

Enfermedad investigada
Non segmental vitiligo

Título Científico
A Phase 2a, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of MK-6194 in Adult Participants with Non-Segmental Vitiligo.

Justificación

No aportado

Objetivo Principal

1.To evaluate the efficacy of MK-6194 on the percent change from baseline in Facial Vitiligo Area Scoring Index (F-VASI) at Week 24
2.To evaluate the safety and tolerability of MK-6194

Variables de Evaluación Primaria

Change from Baseline in Facial Vitiligo Area Scoring Index (F-VASI) at Week 24
Number of Participants Who Experience an Adverse Event (AE)
Number of Participants Who Discontinue Study Treatment Due to an AE

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

1.To evaluate the efficacy of MK-6194 on the percent change from baseline in Total Vitiligo Area Scoring Index (T-VASI) at Week 24

Variables de Evaluación Secundaria

Change from Baseline in Total Vitiligo Area Scoring Index (T-VASI) at Week 24

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Has a clinical diagnosis of non-segmental vitiligo
Has non-segmental vitiligo with disease duration of at least 6 months
Has depigmentation contributing to F-VASI 0.3 at screening and baseline
Has depigmented facial body surface area (BSA) 0.3% at screening and baseline
Has T-VASI 4 at screening and baseline

Has total body vitiligo area 4% at screening and baseline excluding hands and feet involvement
Is 18 to 75 years of age inclusive at the time of providing informed consent

Criterios de Exclusión

Has segmental vitiligo
Has a history of any malignancy, except for successfully treated non-melanoma skin cancer or localized carcinoma in situ of the cervix
Has evidence of active tuberculosis (TB), latent TB, or inadequately treated TB
Has confirmed or suspected COVID-19 infection
Has history of drug or alcohol abuse within 6 months prior to Screening
Has had major surgery within 3 months prior to Screening OR has a major surgery planned during the study
Has had an inadequate response (as evaluated by a dermatologist or local physician specialist equivalent) to previous treatment with a Janus kinase inhibitor (JAKi) after an appropriate treatment duration (eg, 12 weeks)
Has received prohibited medications within protocol-specified timeframes prior to Randomization
Has participated in another investigational clinical study within 4 weeks prior to Randomization
Has donated or lost 1 unit of blood (approximately 500 mL) within 4 weeks prior to the Screening Visit
Has received cosmetic or other procedures that could interfere with evaluation of vitiligo during the study
Has 50% leukotrichia on face or body
Has any other dermatological diseases that would interfere with vitiligo assessments
Has history of or current inflammatory condition other than vitiligo that, in the opinion of the investigator, could interfere with the evaluation of vitiligo
Has a known systemic hypersensitivity to interleukin 2 (IL-2), or modified IL-2 including MK-6194, or its inactive ingredients
Has an active or clinically significant infection, requiring hospitalization or treatment with intravenous (IV) anti-infectives within 4 weeks prior to Randomization, or oral/intramuscular anti-infective therapy within 2 weeks prior to Randomization
Has symptomatic heart failure (New York Heart Association class III or IV) or myocardial infarction or unstable angina pectoris within 6 months prior to Screening
Has a severe chronic pulmonary disease requiring oxygen therapy
Has a transplanted organ, which requires continued immunosuppression

Calendario

(Última actualización: 03/11/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
22/12/2023	01/02/2024	15/03/2024	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
11/09/2024	30/06/2026	No aportado	No aportado	30/07/2025

Promotor

Merck Sharp & Dohme LLC United States

126 East Lincoln Avenue

Contact Person

Claudia Kaiser-Albers

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claudia.kaiser-albers@msd.de

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm de la Comunidad Foral de Navarra

C/ Irunlarrea, 3 31008 Pamplona

ceic@cfnavarra.es

Centros

Cerrado (03/11/2025)

Bellvitge University Hospital

L'hospitalet De Llobregat

BARCELONA

Dermatología

No iniciado (--/--/----)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Dermatología

Cerrado (31/10/2025)

Clinica Universidad De Navarra

Madrid

MADRID

Dermatología

Cerrado (31/10/2025)

Hospital Universitario Puerta Del Mar

Cadiz

CÁDIZ

Dermatología

Medicamentos

MK-6194
SOLUTION FOR INJECTION
SOLUTION FOR INJECTION

-

Principios Activos: N/A

Experimental

Tiene resultados

A clinical study of MK-6194 for the treatment of vitiligo (MK-6194-007)

State	Type of participants	Age Ranges
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	134
Results	**Low level of intervention**	**Rare disease**
Has results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics, pharmacogenetics, pharmacoeconomic	NO

Information

Identifier
2023-503502-37-00 (CTIS)

Protocol Code
MK-6194-007

Therapeutic area
Diseases [C] - Immune System Diseases [C20]|

Investigated Disease
Non segmental vitiligo

Scientific Title
A Phase 2a, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of MK-6194 in Adult Participants with Non-Segmental Vitiligo.

Rationale

Not provided

Main Objective

1.To evaluate the efficacy of MK-6194 on the percent change from baseline in Facial Vitiligo Area Scoring Index (F-VASI) at Week 24
2.To evaluate the safety and tolerability of MK-6194

Primary Endpoints

Change from Baseline in Facial Vitiligo Area Scoring Index (F-VASI) at Week 24
Number of Participants Who Experience an Adverse Event (AE)
Number of Participants Who Discontinue Study Treatment Due to an AE

Temporary moments of secondary assessment

Not provided

Secondary Objective

1.To evaluate the efficacy of MK-6194 on the percent change from baseline in Total Vitiligo Area Scoring Index (T-VASI) at Week 24

Secondary Endpoints

Change from Baseline in Total Vitiligo Area Scoring Index (T-VASI) at Week 24

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Has a clinical diagnosis of non-segmental vitiligo
Has non-segmental vitiligo with disease duration of at least 6 months
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Has depigmented facial body surface area (BSA) 0.3% at screening and baseline
Has T-VASI 4 at screening and baseline

Has total body vitiligo area 4% at screening and baseline excluding hands and feet involvement
Is 18 to 75 years of age inclusive at the time of providing informed consent

Exclusion criteria

Has segmental vitiligo
Has a history of any malignancy, except for successfully treated non-melanoma skin cancer or localized carcinoma in situ of the cervix
Has evidence of active tuberculosis (TB), latent TB, or inadequately treated TB
Has confirmed or suspected COVID-19 infection
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Has a transplanted organ, which requires continued immunosuppression

Calendar

(Last Update: 03/11/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
22/12/2023	01/02/2024	15/03/2024	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
11/09/2024	30/06/2026	Not aported	Not aported	30/07/2025

Sponsor

Merck Sharp & Dohme LLC United States

126 East Lincoln Avenue

Contact Person

Claudia Kaiser-Albers

+491733281166

claudia.kaiser-albers@msd.de

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm de la Comunidad Foral de Navarra

C/ Irunlarrea, 3 31008 Pamplona

ceic@cfnavarra.es

Sites

Closed (03/11/2025)

Bellvitge University Hospital

L'hospitalet De Llobregat

BARCELONA

Dermatología

not initialized (--/--/----)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Dermatología

Closed (31/10/2025)

Clinica Universidad De Navarra

Madrid

MADRID

Dermatología

Closed (31/10/2025)

Hospital Universitario Puerta Del Mar

Cadiz

CÁDIZ

Dermatología

Medication

MK-6194

SOLUTION FOR INJECTION

SOLUTION FOR INJECTION

-

Active Principles: N/A

Experimental

Has results