A Phase 3, Parallel Group Study to Evaluate KarXT as a Treatment for Psychosis Associated with Alzheimers Disease

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	Sujetos incapaces de otorgar consentimiento	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	256
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética	NO

Información

Identificador
2024-516363-92-00 (CTIS)

Cod. Protocolo
CN0120056

Área terapéutica
·Psiquiatría y Psicología [F] - Desórdenes mentales [F03]
·Enfermedades [C] - Sistema Nervioso [C10]

Enfermedad investigada
Psychosis Associated with Alzheimers Disease

Título Científico
A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Safety and Efficacy of KarXT for the Treatment of Psychosis Associated with Alzheimers Disease (ADEPT-4)

Justificación

No aportado

Objetivo Principal

The main objectives of the trial are to evaluate the efficacy of KarXT compared with placebo in the treatment of psychosis in participants with psychosis associated with AD as measured by the Neuropsychiatric Inventory-Clinician (NPI-C):Hallucinations and Delusions (H+D) score

Variables de Evaluación Primaria

The main endpoint is the change from Baseline to End of Treatment in NPI-C: H+D score.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the efficacy of KarXT compared with placebo in the treatment of psychosis in participants with psychosis associated with AD as measured by the CGI-S scale: CGI-S requires the assessor to consider aspects of the psychosis (hallucinations and delusions) prior to providing a global assessment of severity.

Variables de Evaluación Secundaria

The key secondary endpoint is the change from Baseline to End of Treatment on CGI-S score.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Patients who are 55-90 years old
A diagnosis of AD in accordance with the 2024 revised criteria for diagnosis and staging of Alzheimers Disease: Alzheimers Association Workgroup
Participants who have a magnetic resonance imaging (MRI) or computed tomography (CT) scan of the brain (completed within the past 5 years) taken during or subsequent to the onset of dementia to rule out other central nervous system (CNS) disease that could account for the dementia syndrome, eg, major stroke, neoplasm, subdural

hematoma
Patient must have a history of psychotic symptoms (meeting International Psychogeriatric Association criteria) for at least 2 months prior to Screening (Visit 1) (participants may or may not have symptoms of agitation)

Criterios de Exclusión

Patients will not be able to participate if they have psychotic symptoms that are primarily attributable to a condition other than the AD causing the dementia, eg, schizophrenia, schizoaffective disorder, delusional disorder, or mood disorder with psychotic features.
History of major depressive episode with psychotic features during the 12 months prior to Screening, or history of bipolar disorder, schizophrenia, or schizoaffective disorder.
Patients are not able to participate if they have certain safety concerns, including certain laboratory test irregularities.

Calendario

(Última actualización: 30/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
26/03/2025	08/04/2025	09/04/2025	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
No aportado	No aportado	No aportado	No aportado	No aportado

Promotor

Bristol-Myers Squibb Services Unlimited Company Ireland

Plaza 254 Blanchardstown Corporate Park 2

Contact Person

GSM-CT

003223527611

mg-gsm-ct@bms.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Clínico San Carlos

C/ Doctor Martín Lagos, s/n - Ciudad Universitaria 28040 Madrid

ceic.hcsc@salud.madrid.org

917044160

Centros

Activo (30/03/2026)

Clinica Montecanal S.L.

Zaragoza

ZARAGOZA

Neurology

Activo (09/04/2025)

Hospital Clinico San Carlos

Madrid

MADRID

Neurology

Activo (02/03/2026)

Hospital Quironsalud Malaga

Malaga

MÁLAGA

Neurology

Cerrado (21/05/2026)

Hospital Universitari De Santa Maria

Lleida

LÉRIDA

Neurology

Activo (21/04/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Psychiatry

Activo (08/05/2025)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Neurology

Activo (08/04/2025)

Hospital Universitario Rio Hortega

Valladolid

VALLADOLID

Psychiatry

Activo (22/04/2025)

Hospital Victoria Eugenia De La Cruz Roja Espanola

Sevilla

SEVILLA

Neurology

Medicamentos

KarXT
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

KarXT
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

KarXT
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

KarXT
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

KarXT
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

Sin resultados

A Phase 3, Parallel Group Study to Evaluate KarXT as a Treatment for Psychosis Associated with Alzheimers Disease

State	Type of participants	Age Ranges
Recruiting	Incapable subjects of giving consent	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	256
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2024-516363-92-00 (CTIS)

Protocol Code
CN0120056

Therapeutic area
·Psychiatry and Psychology [F] - Mental Disorders [F03]
·Diseases [C] - Nervous System Diseases [C10]

Investigated Disease
Psychosis Associated with Alzheimers Disease

Scientific Title
A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Safety and Efficacy of KarXT for the Treatment of Psychosis Associated with Alzheimers Disease (ADEPT-4)

Rationale

Not provided

Main Objective

The main objectives of the trial are to evaluate the efficacy of KarXT compared with placebo in the treatment of psychosis in participants with psychosis associated with AD as measured by the Neuropsychiatric Inventory-Clinician (NPI-C):Hallucinations and Delusions (H+D) score

Primary Endpoints

The main endpoint is the change from Baseline to End of Treatment in NPI-C: H+D score.

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the efficacy of KarXT compared with placebo in the treatment of psychosis in participants with psychosis associated with AD as measured by the CGI-S scale: CGI-S requires the assessor to consider aspects of the psychosis (hallucinations and delusions) prior to providing a global assessment of severity.

Secondary Endpoints

The key secondary endpoint is the change from Baseline to End of Treatment on CGI-S score.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Patients who are 55-90 years old
A diagnosis of AD in accordance with the 2024 revised criteria for diagnosis and staging of Alzheimers Disease: Alzheimers Association Workgroup
Participants who have a magnetic resonance imaging (MRI) or computed tomography (CT) scan of the brain (completed within the past 5 years) taken during or subsequent to the onset of dementia to rule out other central nervous system (CNS) disease that could account for the dementia syndrome, eg, major stroke, neoplasm, subdural

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Exclusion criteria

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History of major depressive episode with psychotic features during the 12 months prior to Screening, or history of bipolar disorder, schizophrenia, or schizoaffective disorder.
Patients are not able to participate if they have certain safety concerns, including certain laboratory test irregularities.

Calendar

(Last Update: 30/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
26/03/2025	08/04/2025	09/04/2025	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
Not aported	Not aported	Not aported	Not aported	Not aported

Sponsor

Bristol-Myers Squibb Services Unlimited Company Ireland

Plaza 254 Blanchardstown Corporate Park 2

Contact Person

GSM-CT

003223527611

mg-gsm-ct@bms.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

Active (30/03/2026)

Clinica Montecanal S.L.

Zaragoza

ZARAGOZA

Neurology

Active (09/04/2025)

Hospital Clinico San Carlos

Madrid

MADRID

Neurology

Active (02/03/2026)

Hospital Quironsalud Malaga

Malaga

MÁLAGA

Neurology

Closed (21/05/2026)

Hospital Universitari De Santa Maria

Lleida

LÉRIDA

Neurology

Active (21/04/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Psychiatry

Active (08/05/2025)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Neurology

Active (08/04/2025)

Hospital Universitario Rio Hortega

Valladolid

VALLADOLID

Psychiatry

Active (22/04/2025)

Hospital Victoria Eugenia De La Cruz Roja Espanola

Sevilla

SEVILLA

Neurology

Medication

KarXT
CAPSULE
ORAL

-
Active Principles: N/A

Experimental

KarXT
CAPSULE
ORAL

-
Active Principles: N/A

Experimental

KarXT
CAPSULE
ORAL

-
Active Principles: N/A

Experimental

KarXT
CAPSULE
ORAL

-
Active Principles: N/A

Experimental

KarXT
CAPSULE
ORAL

-
Active Principles: N/A

Experimental

No results