A Study to Assess the Anti-Tumor Activity and Safety of Odronextamab in Adult Patients With B-cell Non-Hodgkin Lymphoma Who Have Been Previously Treated with Other Cancer Therapies

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	315
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica, dosis	NO

Información

Identificador
2024-511747-25-00 (CTIS)

Cod. Protocolo
R1979-ONC-1625

Transicionado 2017-002139-41

Área terapéutica
Enfermedades [C] - Hematología [C15]|

Enfermedad investigada
B-cell non-Hodgkin lymphoma (NHL)

Título Científico
AN OPEN-LABEL STUDY TO ASSESS THE ANTI-TUMOR ACTIVITY AND SAFETY OF REGN1979, AN ANTI CD20 X ANTI-CD3 BISPECIFIC ANTIBODY, IN PATIENTS WITH RELAPSED OR REFRACTORY B CELL NON-HODGKIN LYMPHOMA

Justificación

No aportado

Objetivo Principal

To assess the anti-tumor activity of single agent Odronextamab as measured by the objective response rate (ORR) according to the Lugano Classification of response in malignant lymphoma and as assessed by independent central review in each of the following B-cell non-Hodgkin lymphoma (B-NHL) subgroups:
- In patients with follicular lymphoma (FL) grade 1-3a that has relapsed after or is refractory to at least 2 prior lines of systemic therapy including an anti-CD20 antibody and an alkylating agent
- In patients with diffuse large B-cell lymphoma (DLBCL) that has relapsed after or is refractory to at least 2 prior lines of systemic therapy including an anti-CD20 antibody and an alkylating agent
- In patients with mantle cell lymphoma (MCL) who have relapsed or refractory disease to at least one prior line of systemic therapy and had prior Brutons tyrosine kinase (BTK) inhibitor treatment.
- In patients with marginal zone lymphoma (MZL) that has relapsed after or is refractory to at least 2 prior lines of systemic therapy
- In patients with other B-NHL subtypes that has relapsed after or is refractory to at least 2 prior lines of systemic therapy

Variables de Evaluación Primaria

The primary endpoint of the study for each of the 5 disease-specific cohorts is as follows: ORR according to the Lugano Classification of response in malignant lymphoma (Cheson, 2014) and as assessed by independent central review.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To assess the anti-tumor activity of single agent odronextamab in each of 5 disease-specific cohorts, as measured by ORR according to the Lugano Classification and as assessed by local investigator evaluation
To assess the anti-tumor activity of single agent odronextamab in each of 5 disease-specific cohorts, as measured by complete response (CR) rate according to the Lugano Classification and as assessed local by local investigator evaluation and independent central review
To assess the anti-tumor activity of single agent odronextamab in each of 5 disease-specific cohorts, as measured by progression-free survival (PFS) according to Lugano Classification and as assessed by independent central review and local investigator evaluation
To assess the anti-tumor activity of single agent odronextamab in each of 5 disease-specific cohorts, as measured by overall survival (OS)
To assess the anti-tumor activity of single agent odronextamab in each of 5 disease-specific cohorts, as measured by duration of response (DOR) according to Lugano Classification and as assessed by independent central review and local investigator evaluation
To assess the anti-tumor activity of single agent odronextamab in each of 5 disease-specific cohorts, as measured by disease control rate (DCR) according to Lugano Classification and as assessed by independent central review

and local investigator evaluation
To evaluate the safety and tolerability of odronextamab
To assess the pharmacokinetics (PK) of Odronextamab
To assess the immunogenicity of Odronextamab
To assess the effect of Odronextamab on patient reported outcomes, including health-related quality of life (HRQL), as measured by the validated instruments European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30), Functional Assessment of Cancer Therapy-Lymphoma (FACT-Lym), and EuroQoL 5 Dimensions 3 Levels (EQ-5D-3L)

Variables de Evaluación Secundaria

ORR according to the Lugano Classification and as assessed by local investigator evaluation
Complete response (CR) rate according to the Lugano Classification and as assessed by local investigator evaluation and independent central review.
Progression free survival (PFS) according to the Lugano Classification and as assessed by independent central review and local investigator evaluation
Overall survival (OS)
Duration of response (DOR) according to the Lugano Classification and as assessed by independent central review and local investigator evaluation
Disease control rate (DCR) according to the Lugano Classification and as assessed by independent central review and local investigator evaluation by independent central review and local investigator evaluation
Incidence and severity of treatment emergent adverse events (TEAEs)
Pharmacokinetics: concentration of odronextamab, incidence of anti-drug antibodies (ADA) to odronextamab over time, incidence of neutralizing antibodies (Nab) to odronextamab over time
Changes in scores of patient-reported outcomes as measured by EORTC QLQ-C30
Changes in scores of patient-reported outcomes as measured by FACT-Lym
Changes in scores of patient-reported outcomes as measured by EQ-5D-3L

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

For the FL grade 1-3a cohort only: Central histopathologic confirmation of the FL Grade 1 to 3a diagnosis must be obtained before study enrollment. Patients with FL grade 3b are ineligible for this cohort but may be included in the "other B-NHL" cohort. Follicular lymphoma subtyping is based on the World Health Organization (WHO) classification
Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
Other protocol-defined inclusion criteria apply
Adequate bone marrow, hepatic, and renal function as defined in the protocol
Disease-specific cohorts: Patients should in the judgment of the investigator require systemic therapy for lymphoma at the time of study enrollment. FL grade 1-3a cohort: Patients with FL grade 1-3a that has relapsed after or is refractory to at least 2 prior lines of systemic therapy, as defined in the protocol
DLBCL cohort: Patients with DLBCL that has relapsed after or is refractory to at least 2 prior lines of systemic therapy as defined in the protocol
MCL after BTK inhibitor therapy cohort: Patients with MCL who have relapsed or refractory disease to at least one prior line of systemic therapy and had prior treatment with a BTK inhibitor.
MZL cohort: Patients with MZL that have relapsed or is refractory to at least 2 prior lines of systemic therapy.
Other B-NHL cohort: Patients with B-NHL other than FL grade 1-3a, DLBCL, MCL, or MZL that has relapsed after or

is refractory to at least 2 prior lines of systemic therapy as defined in the protocol. New enrollment stopped for patients with Burkitt lymphoma and Burkitt-like lymphoma.
Patients should in the judgment of the investigator require systemic therapy for lymphoma at the time of study enrollment
Measurable disease on cross sectional imaging as defined in the protocol documented by diagnostic imaging (computed tomography (CT), or magnetic resonance imaging (MRI)

Criterios de Exclusión

Primary central nervous system (CNS) lymphoma or known involvement by non-primary CNS Non-Hodgkin Lymphoma (NHL) (suspected CNS lymphoma should be evaluated by lumbar puncture, as appropriate, in addition to the mandatory head CT or MRI).
Prior treatment with an anti-CD20 x anti-CD3 bispecific therapy
Other protocol-defined exclusion criteria apply
Treatment with any systemic anti-lymphoma therapy within 5 half-lives or within 28 days prior to first administration of study drug, whichever is shorter.
History of allogeneic stem cell transplantation
Criterion removed
Continuous systemic corticosteroid treatment with more than 10 mg per day of prednisone or anti-inflammatory equivalent within 72 hours of start of study drug
History of neurodegenerative condition or CNS movement disorder. Patients with a history of seizure within 12 months prior to study enrollment are excluded
Another malignancy except B-NHL in the past 5 years, with the exception of non-melanoma skin cancer that has undergone potentially curative therapy or in situ cervical carcinoma, or any other tumor that has been deemed to be effectively treated with definitive local control and with curative intent.
Uncontrolled infection with human immunodeficiency virus (HIV), hepatitis B or hepatitis C infection; cytomegalovirus (CMV) infection as noted by detectable levels on a blood polymerase chain reaction (PCR) assay as defined in the protocol or other uncontrolled infections
Known hypersensitivity to both allopurinol and rasburicase

Calendario

(Última actualización: 30/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
24/07/2019	26/02/2020	26/02/2020	10/12/2020	15/07/2021

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
10/09/2025	No aportado	No aportado	No aportado	No aportado

Promotor

Regeneron Pharmaceuticals Inc. United States

777 Old Saw Mill River Road

Contact Person

Head EU Regulatory Affairs

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medical.information_EU@regeneron.com

Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Cerrado (29/11/2023)

CENTRO ONCOLÓGICO MD ANDERSON INTERNATIONAL ESPAÑA

Madrid

MADRID

Servicio de Hematologia

Activo (20/02/2020)

COMPLEJO ASISTENCIAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Servicio de Hematologia

Activo (10/01/2020)

HOSPITAL CLÍNIC DE BARCELONA

Barcelona

BARCELONA

Servicio de Hematologia

Cerrado (18/12/2023)

HOSPITAL COSTA DEL SOL

Marbella

MÁLAGA

Servicio de Hematologia

Activo (13/12/2019)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

Servicio de Hematologia

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

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Clinical hematology

Activo (19/02/2020)

HOSPITAL QUIRÓNSALUD MADRID

Pozuelo de Alarcón

MADRID

Servicio de Hematologia

Cerrado (06/11/2023)

HOSPITAL SON LLATZER

Palma de Mallorca

BALEARES

Servicio de Hematologia

Activo (29/01/2020)

HOSPITAL UNIVERSITARI SON ESPASES

Palma de Mallorca

BALEARES

Servicio de Hematologia

Activo (23/01/2020)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Servicio de Hematologia

Cerrado (29/06/2022)

HOSPITAL UNIVERSITARIO DONOSTIA-DONOSTIA UNIBERTSITATE OSPITALEA

Donostia/San Sebastián

GUIPÚZCOA

Servicio de Hematologia

Activo (03/06/2020)

HOSPITAL UNIVERSITARIO FUNDACIÓN JIMÉNEZ DÍAZ

Madrid

MADRID

Servicio de Hematologia

Activo (20/12/2019)

HOSPITAL UNIVERSITARIO MADRID SANCHINARRO

Madrid

MADRID

Servicio de Hematologia

Activo (28/01/2020)

HOSPITAL UNIVERSITARIO Y POLITÉCNICO LA FE

Valencia

VALENCIA

Servicio de Hematologia

Activo (03/06/2020)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Servicio de Hematologia

Activo (22/01/2021)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Servicio de Oncología

Medicamentos

Odronextamab
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-
Principios Activos: N/A
Huérfano Experimental

Odronextamab
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

Código ATC: L01FX34 - ODRONEXTAMAB
Principios Activos: N/A
Huérfano Experimental

Odronextamab
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-
Principios Activos: N/A
Huérfano Experimental

Sin resultados

A Study to Assess the Anti-Tumor Activity and Safety of Odronextamab in Adult Patients With B-cell Non-Hodgkin Lymphoma Who Have Been Previously Treated with Other Cancer Therapies

State	**Type of participants**	**Age Ranges**
End of recruitment	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	315
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics, dose	NO

Information

Identifier

2024-511747-25-00 (CTIS)

Protocol Code

R1979-ONC-1625

Transitioned 2017-002139-41

Therapeutic area

Diseases [C] - Hemic and Lymphatic Diseases [C15]|

Investigated Disease

B-cell non-Hodgkin lymphoma (NHL)

Scientific Title

AN OPEN-LABEL STUDY TO ASSESS THE ANTI-TUMOR ACTIVITY AND SAFETY OF REGN1979, AN ANTI CD20 X ANTI-CD3 BISPECIFIC ANTIBODY, IN PATIENTS WITH RELAPSED OR REFRACTORY B CELL NON-HODGKIN LYMPHOMA

Rationale

Not provided

Main Objective

To assess the anti-tumor activity of single agent Odronextamab as measured by the objective response rate (ORR) according to the Lugano Classification of response in malignant lymphoma and as assessed by independent central review in each of the following B-cell non-Hodgkin lymphoma (B-NHL) subgroups:
- In patients with follicular lymphoma (FL) grade 1-3a that has relapsed after or is refractory to at least 2 prior lines of systemic therapy including an anti-CD20 antibody and an alkylating agent
- In patients with diffuse large B-cell lymphoma (DLBCL) that has relapsed after or is refractory to at least 2 prior lines of systemic therapy including an anti-CD20 antibody and an alkylating agent
- In patients with mantle cell lymphoma (MCL) who have relapsed or refractory disease to at least one prior line of systemic therapy and had prior Brutons tyrosine kinase (BTK) inhibitor treatment.
- In patients with marginal zone lymphoma (MZL) that has relapsed after or is refractory to at least 2 prior lines of systemic therapy
- In patients with other B-NHL subtypes that has relapsed after or is refractory to at least 2 prior lines of systemic therapy

Primary Endpoints

The primary endpoint of the study for each of the 5 disease-specific cohorts is as follows: ORR according to the Lugano Classification of response in malignant lymphoma (Cheson, 2014) and as assessed by independent central review.

Temporary moments of secondary assessment

Not provided

Secondary Objective

To assess the anti-tumor activity of single agent odronextamab in each of 5 disease-specific cohorts, as measured by ORR according to the Lugano Classification and as assessed by local investigator evaluation
To assess the anti-tumor activity of single agent odronextamab in each of 5 disease-specific cohorts, as measured by complete response (CR) rate according to the Lugano Classification and as assessed local by local investigator evaluation and independent central review
To assess the anti-tumor activity of single agent odronextamab in each of 5 disease-specific cohorts, as measured by progression-free survival (PFS) according to Lugano Classification and as assessed by independent central review and local investigator evaluation
To assess the anti-tumor activity of single agent odronextamab in each of 5 disease-specific cohorts, as measured by overall survival (OS)
To assess the anti-tumor activity of single agent odronextamab in each of 5 disease-specific cohorts, as measured by duration of response (DOR) according to Lugano Classification and as assessed by independent central review and local investigator evaluation
To assess the anti-tumor activity of single agent odronextamab in each of 5 disease-specific cohorts, as measured by disease control rate (DCR) according to Lugano Classification and as assessed by independent central review

and local investigator evaluation
To evaluate the safety and tolerability of odronextamab
To assess the pharmacokinetics (PK) of Odronextamab
To assess the immunogenicity of Odronextamab
To assess the effect of Odronextamab on patient reported outcomes, including health-related quality of life (HRQL), as measured by the validated instruments European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30), Functional Assessment of Cancer Therapy-Lymphoma (FACT-Lym), and EuroQoL 5 Dimensions 3 Levels (EQ-5D-3L)

Secondary Endpoints

ORR according to the Lugano Classification and as assessed by local investigator evaluation
Complete response (CR) rate according to the Lugano Classification and as assessed by local investigator evaluation and independent central review.
Progression free survival (PFS) according to the Lugano Classification and as assessed by independent central review and local investigator evaluation
Overall survival (OS)
Duration of response (DOR) according to the Lugano Classification and as assessed by independent central review and local investigator evaluation
Disease control rate (DCR) according to the Lugano Classification and as assessed by independent central review and local investigator evaluation by independent central review and local investigator evaluation
Incidence and severity of treatment emergent adverse events (TEAEs)
Pharmacokinetics: concentration of odronextamab, incidence of anti-drug antibodies (ADA) to odronextamab over time, incidence of neutralizing antibodies (Nab) to odronextamab over time
Changes in scores of patient-reported outcomes as measured by EORTC QLQ-C30
Changes in scores of patient-reported outcomes as measured by FACT-Lym
Changes in scores of patient-reported outcomes as measured by EQ-5D-3L

Temporary moments of secondary assessment

Not provided

Inclusion criteria

For the FL grade 1-3a cohort only: Central histopathologic confirmation of the FL Grade 1 to 3a diagnosis must be obtained before study enrollment. Patients with FL grade 3b are ineligible for this cohort but may be included in the "other B-NHL" cohort. Follicular lymphoma subtyping is based on the World Health Organization (WHO) classification
Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
Other protocol-defined inclusion criteria apply
Adequate bone marrow, hepatic, and renal function as defined in the protocol
Disease-specific cohorts: Patients should in the judgment of the investigator require systemic therapy for lymphoma at the time of study enrollment. FL grade 1-3a cohort: Patients with FL grade 1-3a that has relapsed after or is refractory to at least 2 prior lines of systemic therapy, as defined in the protocol
DLBCL cohort: Patients with DLBCL that has relapsed after or is refractory to at least 2 prior lines of systemic therapy as defined in the protocol
MCL after BTK inhibitor therapy cohort: Patients with MCL who have relapsed or refractory disease to at least one prior line of systemic therapy and had prior treatment with a BTK inhibitor.
MZL cohort: Patients with MZL that have relapsed or is refractory to at least 2 prior lines of systemic therapy.
Other B-NHL cohort: Patients with B-NHL other than FL grade 1-3a, DLBCL, MCL, or MZL that has relapsed after or

is refractory to at least 2 prior lines of systemic therapy as defined in the protocol. New enrollment stopped for patients with Burkitt lymphoma and Burkitt-like lymphoma.
Patients should in the judgment of the investigator require systemic therapy for lymphoma at the time of study enrollment
Measurable disease on cross sectional imaging as defined in the protocol documented by diagnostic imaging (computed tomography (CT), or magnetic resonance imaging (MRI)

Exclusion criteria

Primary central nervous system (CNS) lymphoma or known involvement by non-primary CNS Non-Hodgkin Lymphoma (NHL) (suspected CNS lymphoma should be evaluated by lumbar puncture, as appropriate, in addition to the mandatory head CT or MRI).
Prior treatment with an anti-CD20 x anti-CD3 bispecific therapy
Other protocol-defined exclusion criteria apply
Treatment with any systemic anti-lymphoma therapy within 5 half-lives or within 28 days prior to first administration of study drug, whichever is shorter.
History of allogeneic stem cell transplantation
Criterion removed
Continuous systemic corticosteroid treatment with more than 10 mg per day of prednisone or anti-inflammatory equivalent within 72 hours of start of study drug
History of neurodegenerative condition or CNS movement disorder. Patients with a history of seizure within 12 months prior to study enrollment are excluded
Another malignancy except B-NHL in the past 5 years, with the exception of non-melanoma skin cancer that has undergone potentially curative therapy or in situ cervical carcinoma, or any other tumor that has been deemed to be effectively treated with definitive local control and with curative intent.
Uncontrolled infection with human immunodeficiency virus (HIV), hepatitis B or hepatitis C infection; cytomegalovirus (CMV) infection as noted by detectable levels on a blood polymerase chain reaction (PCR) assay as defined in the protocol or other uncontrolled infections
Known hypersensitivity to both allopurinol and rasburicase

Calendar

(Last Update: 30/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
24/07/2019	26/02/2020	26/02/2020	10/12/2020	15/07/2021

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
10/09/2025	Not aported	Not aported	Not aported	Not aported

Sponsor

Regeneron Pharmaceuticals Inc. United States

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Contact Person

Head EU Regulatory Affairs

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medical.information_EU@regeneron.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

Closed (29/11/2023)

CENTRO ONCOLÓGICO MD ANDERSON INTERNATIONAL ESPAÑA

Madrid

MADRID

Servicio de Hematologia

Active (20/02/2020)

COMPLEJO ASISTENCIAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Servicio de Hematologia

Active (10/01/2020)

HOSPITAL CLÍNIC DE BARCELONA

Barcelona

BARCELONA

Servicio de Hematologia

Closed (18/12/2023)

HOSPITAL COSTA DEL SOL

Marbella

MÁLAGA

Servicio de Hematologia

Active (13/12/2019)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

Servicio de Hematologia

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

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Clinical hematology

Active (19/02/2020)

HOSPITAL QUIRÓNSALUD MADRID

Pozuelo de Alarcón

MADRID

Servicio de Hematologia

Closed (06/11/2023)

HOSPITAL SON LLATZER

Palma de Mallorca

BALEARES

Servicio de Hematologia

Active (29/01/2020)

HOSPITAL UNIVERSITARI SON ESPASES

Palma de Mallorca

BALEARES

Servicio de Hematologia

Active (23/01/2020)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Servicio de Hematologia

Closed (29/06/2022)

HOSPITAL UNIVERSITARIO DONOSTIA-DONOSTIA UNIBERTSITATE OSPITALEA

Donostia/San Sebastián

GUIPÚZCOA

Servicio de Hematologia

Active (03/06/2020)

HOSPITAL UNIVERSITARIO FUNDACIÓN JIMÉNEZ DÍAZ

Madrid

MADRID

Servicio de Hematologia

Active (20/12/2019)

HOSPITAL UNIVERSITARIO MADRID SANCHINARRO

Madrid

MADRID

Servicio de Hematologia

Active (28/01/2020)

HOSPITAL UNIVERSITARIO Y POLITÉCNICO LA FE

Valencia

VALENCIA

Servicio de Hematologia

Active (03/06/2020)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Servicio de Hematologia

Active (22/01/2021)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Servicio de Oncología

Medication

Odronextamab
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-

Active Principles: N/A

Orphan Experimental

Odronextamab
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

ATC code: L01FX34 - ODRONEXTAMAB

Active Principles: N/A

Orphan Experimental

Odronextamab
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-

Active Principles: N/A

Orphan Experimental

No results