Clinical trial to evaluate the efficacy and safety of pirtobrutinib in combination with rituximab in patients with indolent clinical forms of Mantle Cell Lymphoma

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	0
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia	NO

Información

Identificador
2024-511983-97-00 (CTIS)

Cod. Protocolo
IMCL-2023

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

Enfermedad investigada
Adult patients with indolent MCL who have not previously received treatment (naïve patients).

Título Científico
International multicentric phase II trial to evaluate the efficacy and safety of pirtobrutinib in combination with rituximab in patients with indolent clinical forms of Mantle Cell Lymphoma

Justificación

No aportado

Objetivo Principal

To assess the activity of Pirtobrutinib in combination with rituximab (P-R) as a therapeutic alternative to immunochemotherapy (R-Bendamustine or R-CHOP regimen) in patients with an indolent clinical presentation of MCL.

Variables de Evaluación Primaria

Primary objective point will be assessed by the complete remission rate (CRR), defined as the percentage of patients who achieve a complete response (CR) at the end of Cycle 6 of the P-R combination according to the Lugano Classification (Appendix 3)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

1. To evaluate the activity of P-R combination along time in terms of ORR, CRR at 12 and 24 months, MRD response, clinical and molecular response duration and survival.
2. To evaluate and compare the MRD detection ability of different MRD assays.
3. To determine the safety and tolerability of P-R combination
4. To assess the patient Health-related Quality of Life (HRQoL)
5. To perform a comprehensive biological characterization of cases with an indolent clinical presentation of MCL, including their mechanisms of response and resistance to P-R, their clonal evolution until progression or relapse by means of longitudinal studies based on bulk and single-cell level multi-omic techniques.

Variables de Evaluación Secundaria

The activity of P-R combination will be assessed in the overall population according to the Lugano Classification
The sensitivity, specificity, false positive and negative rates of MRD assays: Allele-specific oligonucleotide real-time quantitative Polymerase chain reaction (ASO-qPCR) and New Generation Sequencing (NGS) based assays.
The safety of P-R combination will be assessed by terms of Adverse Events (AEs), Severe Adverse Events (SAEs), Suspected Unexpected Adverse Reactions (SUSARs) during the P-R treatment. All AEs will be classified according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.
The changes in the total score between baseline and 6, 12, and 24 months and End of Study (EoS) respectively in patient HRQoL measured by patient reported outcomes (PROs): The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 items (EORTC-QLQ-C30), and The Functional Assessment of Cancer Therapy-Lymphoma (FACT)-Lym questionnaire.
Longitudinal characterization of tumor samples prior to onset of P-R and at relapse or progression (peripheral blood,

plasma, bone marrow and lymph node or other tissues involved) in addition to the study of sequential semestral peripheral blood and plasma samples. The biological characterization will include bulk and single-cell level multi-omics techniques.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Adult patients (18 years of age). Stable disease without evidence of clinical progression for at least 3 months. Patients in prolonged observation may be included (over 3 months). Female patients of child-bearing potential must have a negative serum pregnancy test at screening and agree to use highly effective contraception from the start of study treatment (See Appendix 4), during the treatment period and for at least 1 month following the last dose of pirtobrutinib and for 12 months following treatment with Rituximab Male patients must use highly effective contraception (if sexually active with a female of child-bearing potential) according to the recommendations provided by the Clinical Trial Facilitation and Coordination Group (CTFG), from start of study treatment, during the treatment period, and for at least 1 month following the last dose of pirtobrutinib and for 12 months following treatment with rituximab. Willing and capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in the protocol Not included in other clinical trial or treated with an experimental drug unrelated to MCL within the past 2 years. Written informed consent must be obtained before any study-specific assessment is performed. Subjects with confirmed diagnosis of Mantle Cell Lymphoma according to the International Consensus Classification, (ICC) 2022] or World Health Organization (WHO) Classification 2022. Classical, small-cell variants and marginal-zone variants can be included. Naïve patients for MCL management (no prior therapies, excluding diagnostic splenectomy) Asymptomatic patients Eastern Cooperative Oncology Group (ECOG) performance status <2 (0 -1) Clinical stage I-IV according to the Ann Arbor classification with no symptoms attributable to MCL Patients with a leukemic non-nodal presentation with mainly bone marrow or peripheral blood involvement are eligible. Other asymptomatic clinical presentations are acceptable in case of low tumour burden, including MCL with lymph node enlargement 3 cm in the largest diameter and with low proliferation index (Ki67 < 30%) The following laboratory values at screening: Neutrophil count 1×109/L, Haemoglobin level 100 g/L and platelet count 100×109/L Transaminases (AST and ALT) 3 x ULN Total bilirubin 1.5 x ULN unless bilirubin rise is due to Gilberts disease Calculated creatinine clearance 30 ml/min according to Cockcroft/Gault Formula (140 age) × body weight (kg) × 0.85 (if female)/ serum creatinine (mg/dL) × 72 Adequate coagulation, defined as activated partial thromboplastin time (aPTT) or partial thromboplastin time (PTT) and prothrombin (PT) or (international normalized ratio (INR) not greater than 1.5 x ULN.

Criterios de Exclusión

Subjects with aggressive histological variants: blastoid and pleomorphic variants of MCL History of bleeding diathesis Past medical history of stroke or intracranial haemorrhage within 6 months prior to inclusion. Significant cardiovascular disease defined as: i) unstable angina or acute coronary syndrome within the past 2 months prior to randomization; ii) history of myocardial infarction within 3 months prior to randomization or documented LVEF by any method of 40% in the 12 months prior to inclusion; iii) Grade 3 NYHA functional classification system of heart failure; iv) Uncontrolled or symptomatic arrhythmias. Prolongation of the QT interval corrected for heart rate (QTcF) > 470 msec. QTcF is calculated using Fridericias Formula (QTcF): QTcF = QT/(RR0.33). Correction of suspected drug-induced QTcF prolongation can be attempted at the investigators discretion and only if clinically safe to do so with either discontinuation of the offending drug or switch to another drug not known to be associated with QTcF prolongation. Correction for underlying bundle branch block (BBB) allowed. NOTE: Patients with pacemakers are eligible if they have no history of fainting or clinically relevant arrhythmias while using the pacemaker Patients who

have tested positive for Human Immunodeficiency Virus (HIV) are excluded due to risk of opportunistic infections with both HIV and BTK inhibitors. For patients with unknown HIV status, HIV testing will be performed at Screening and result must be negative for enrolment. Known active hepatitis B virus (HBV) infection based on criteria below: Patients with positive hepatitis B surface antigen (HBsAg) are excluded. Patients with positive hepatitis B core antibody (anti-HBc) and negative HBsAg require a negative hepatitis B polymerase chain reaction (PCR) evaluation before inclusion. Patients who are HBV DNA PCR positive will be excluded. Prophylactic antiviral treatment will be required in the patients with positive anti-HBc finally eligible. Hepatitis C virus (HCV): positive hepatitis C antibody. If positive hepatitis C antibody result, patient will need to have a negative result for hepatitis C ribonucleic acid (RNA) before inclusion. Patients who are hepatitis C RNA positive will be excluded. Known active cytomegalovirus (CMV) infection. Unknown or negative status are eligible. Concomitant or previous malignancies the last 2 years other than basal skin cancer or in situ uterine cervix cancer. Major surgery within 4 weeks of inclusion. B-cell monoclonal lymphocytosis with MCL phenotype Vaccinated with live, attenuated vaccines within 4 weeks of inclusion. Active uncontrolled auto-immune cytopenia (e.g., autoimmune haemolytic anaemia [AIHA], idiopathic thrombocytopenic purpura [ITP]) for which new therapy was introduced or existing therapy was escalated within the 4 weeks prior to study enrolment to maintain adequate blood counts. Evidence of other clinically significant uncontrolled condition(s) including but not limited to, uncontrolled systemic bacterial, viral, fungal or parasitic infection (except for fungal nail infection), or any other clinically significant active disease process which in the opinion of the investigator may pose a risk for patient participation (screening for chronic conditions is not required). Known hypersensitivity to any of the excipients of Pirtobrutinib or Rituximab or any intended study medications. Females who are pregnant or breastfeeding or plan to become pregnant or initiate breastfeeding during the study or within 1 month of the last dose of pirtobrutinib or 12 months of the last dose of rituximab. Patients unable to take oral medication or with clinically significant active malabsorption syndrome or other condition likely to affect gastrointestinal absorption of the study drug. Presence of B symptoms or any relevant symptoms related to the MCL. Nodal clinical forms with lymph node enlargement > 3 cm (largest diameter). Organ dysfunction related to MCL including creatinine level > 2 mg/dl or altered liver biochemistry (> 3x ULN). Serum LDH over ULN Known central nervous system (CNS) infiltration. Expected MCL therapy requirement in a short time (< 3 months) Anticoagulation requirement with vitamin K antagonists

Calendario

(Última actualización: 04/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
24/06/2025	29/09/2025	30/09/2025	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

Fundacion Geltamo Spain

Avenida Valdecilla Sn

Contact Person

Ana María Méndez

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Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Activo (29/09/2025)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

Activo (29/09/2025)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Activo (29/09/2025)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Activo (01/10/2025)

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Hematology

Activo (29/10/2025)

Hospital Costa Del Sol

Marbella

MÁLAGA

Hematology

Activo (24/11/2025)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology

Activo (20/02/2026)

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Hematology

Activo (30/10/2025)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Activo (29/09/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Activo (29/09/2025)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

Activo (16/01/2026)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

Activo (06/10/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Activo (18/12/2025)

ICO L'HOSPITALET HOSPITAL DURAN I REYNALS

Barcelona

BARCELONA

Hematology

Activo (07/10/2025)

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematology

Medicamentos

MabThera 100 mg concentrate for solution for infusion

SOLUTION FOR INFUSION

INTRAVENOUS INFUSION

Código ATC: L01FA01 - RITUXIMAB

Principios Activos: N/A

Experimental

Jaypirca 100 mg film-coated tablets

FILM-COATED TABLET

ORAL

-

Principios Activos: N/A

Experimental

MabThera 500 mg concentrate for solution for infusion

SOLUTION FOR INFUSION

INTRAVENOUS INFUSION

Código ATC: L01FA01 - RITUXIMAB

Principios Activos: N/A

Experimental

Sin resultados

Clinical trial to evaluate the efficacy and safety of pirtobrutinib in combination with rituximab in patients with indolent clinical forms of Mantle Cell Lymphoma

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	0
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness	NO

Information

Identifier
2024-511983-97-00 (CTIS)

Protocol Code
IMCL-2023

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

Investigated Disease
Adult patients with indolent MCL who have not previously received treatment (naïve patients).

Scientific Title
International multicentric phase II trial to evaluate the efficacy and safety of pirtobrutinib in combination with rituximab in patients with indolent clinical forms of Mantle Cell Lymphoma

Rationale

Not provided

Main Objective

To assess the activity of Pirtobrutinib in combination with rituximab (P-R) as a therapeutic alternative to immunochemotherapy (R-Bendamustine or R-CHOP regimen) in patients with an indolent clinical presentation of MCL.

Primary Endpoints

Primary objective point will be assessed by the complete remission rate (CRR), defined as the percentage of patients who achieve a complete response (CR) at the end of Cycle 6 of the P-R combination according to the Lugano Classification (Appendix 3)

Temporary moments of secondary assessment

Not provided

Secondary Objective

1. To evaluate the activity of P-R combination along time in terms of ORR, CRR at 12 and 24 months, MRD response, clinical and molecular response duration and survival.
2. To evaluate and compare the MRD detection ability of different MRD assays.
3. To determine the safety and tolerability of P-R combination
4. To assess the patient Health-related Quality of Life (HRQoL)
5. To perform a comprehensive biological characterization of cases with an indolent clinical presentation of MCL, including their mechanisms of response and resistance to P-R, their clonal evolution until progression or relapse by means of longitudinal studies based on bulk and single-cell level multi-omic techniques.

Secondary Endpoints

The activity of P-R combination will be assessed in the overall population according to the Lugano Classification
The sensitivity, specificity, false positive and negative rates of MRD assays: Allele-specific oligonucleotide real-time quantitative Polymerase chain reaction (ASO-qPCR) and New Generation Sequencing (NGS) based assays.
The safety of P-R combination will be assessed by terms of Adverse Events (AEs), Severe Adverse Events (SAEs), Suspected Unexpected Adverse Reactions (SUSARs) during the P-R treatment. All AEs will be classified according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.
The changes in the total score between baseline and 6, 12, and 24 months and End of Study (EoS) respectively in patient HRQoL measured by patient reported outcomes (PROs): The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 items (EORTC-QLQ-C30), and The Functional Assessment of Cancer Therapy-Lymphoma (FACT)-Lym questionnaire.
Longitudinal characterization of tumor samples prior to onset of P-R and at relapse or progression (peripheral blood,

plasma, bone marrow and lymph node or other tissues involved) in addition to the study of sequential semestral peripheral blood and plasma samples. The biological characterization will include bulk and single-cell level multi-omics techniques.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Adult patients (18 years of age). Stable disease without evidence of clinical progression for at least 3 months. Patients in prolonged observation may be included (over 3 months). Female patients of child-bearing potential must have a negative serum pregnancy test at screening and agree to use highly effective contraception from the start of study treatment (See Appendix 4), during the treatment period and for at least 1 month following the last dose of pirtobrutinib and for 12 months following treatment with Rituximab Male patients must use highly effective contraception (if sexually active with a female of child-bearing potential) according to the recommendations provided by the Clinical Trial Facilitation and Coordination Group (CTFG), from start of study treatment, during the treatment period, and for at least 1 month following the last dose of pirtobrutinib and for 12 months following treatment with rituximab. Willing and capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in the protocol Not included in other clinical trial or treated with an experimental drug unrelated to MCL within the past 2 years. Written informed consent must be obtained before any study-specific assessment is performed. Subjects with confirmed diagnosis of Mantle Cell Lymphoma according to the International Consensus Classification, (ICC) 2022] or World Health Organization (WHO) Classification 2022. Classical, small-cell variants and marginal-zone variants can be included. Naïve patients for MCL management (no prior therapies, excluding diagnostic splenectomy) Asymptomatic patients Eastern Cooperative Oncology Group (ECOG) performance status <2 (0 -1) Clinical stage I-IV according to the Ann Arbor classification with no symptoms attributable to MCL Patients with a leukemic non-nodal presentation with mainly bone marrow or peripheral blood involvement are eligible. Other asymptomatic clinical presentations are acceptable in case of low tumour burden, including MCL with lymph node enlargement 3 cm in the largest diameter and with low proliferation index (Ki67 < 30%) The following laboratory values at screening: Neutrophil count 1×109/L, Haemoglobin level 100 g/L and platelet count 100×109/L Transaminases (AST and ALT) 3 x ULN Total bilirubin 1.5 x ULN unless bilirubin rise is due to Gilberts disease Calculated creatinine clearance 30 ml/min according to Cockcroft/Gault Formula (140 age) × body weight (kg) × 0.85 (if female)/ serum creatinine (mg/dL) × 72 Adequate coagulation, defined as activated partial thromboplastin time (aPTT) or partial thromboplastin time (PTT) and prothrombin (PT) or (international normalized ratio (INR) not greater than 1.5 x ULN.

Exclusion criteria

Subjects with aggressive histological variants: blastoid and pleomorphic variants of MCL History of bleeding diathesis Past medical history of stroke or intracranial haemorrhage within 6 months prior to inclusion. Significant cardiovascular disease defined as: i) unstable angina or acute coronary syndrome within the past 2 months prior to randomization; ii) history of myocardial infarction within 3 months prior to randomization or documented LVEF by any method of 40% in the 12 months prior to inclusion; iii) Grade 3 NYHA functional classification system of heart failure; iv) Uncontrolled or symptomatic arrhythmias. Prolongation of the QT interval corrected for heart rate (QTcF) > 470 msec. QTcF is calculated using Fridericias Formula (QTcF): QTcF = QT/(RR0.33). Correction of suspected drug-induced QTcF prolongation can be attempted at the investigators discretion and only if clinically safe to do so with either discontinuation of the offending drug or switch to another drug not known to be associated with QTcF prolongation. Correction for underlying bundle branch block (BBB) allowed. NOTE: Patients with pacemakers are eligible if they have no history of fainting or clinically relevant arrhythmias while using the pacemaker Patients who

have tested positive for Human Immunodeficiency Virus (HIV) are excluded due to risk of opportunistic infections with both HIV and BTK inhibitors. For patients with unknown HIV status, HIV testing will be performed at Screening and result must be negative for enrolment. Known active hepatitis B virus (HBV) infection based on criteria below: Patients with positive hepatitis B surface antigen (HBsAg) are excluded. Patients with positive hepatitis B core antibody (anti-HBc) and negative HBsAg require a negative hepatitis B polymerase chain reaction (PCR) evaluation before inclusion. Patients who are HBV DNA PCR positive will be excluded. Prophylactic antiviral treatment will be required in the patients with positive anti-HBc finally eligible. Hepatitis C virus (HCV): positive hepatitis C antibody. If positive hepatitis C antibody result, patient will need to have a negative result for hepatitis C ribonucleic acid (RNA) before inclusion. Patients who are hepatitis C RNA positive will be excluded. Known active cytomegalovirus (CMV) infection. Unknown or negative status are eligible. Concomitant or previous malignancies the last 2 years other than basal skin cancer or in situ uterine cervix cancer. Major surgery within 4 weeks of inclusion. B-cell monoclonal lymphocytosis with MCL phenotype Vaccinated with live, attenuated vaccines within 4 weeks of inclusion. Active uncontrolled auto-immune cytopenia (e.g., autoimmune haemolytic anaemia [AIHA], idiopathic thrombocytopenic purpura [ITP]) for which new therapy was introduced or existing therapy was escalated within the 4 weeks prior to study enrolment to maintain adequate blood counts. Evidence of other clinically significant uncontrolled condition(s) including but not limited to, uncontrolled systemic bacterial, viral, fungal or parasitic infection (except for fungal nail infection), or any other clinically significant active disease process which in the opinion of the investigator may pose a risk for patient participation (screening for chronic conditions is not required). Known hypersensitivity to any of the excipients of Pirtobrutinib or Rituximab or any intended study medications. Females who are pregnant or breastfeeding or plan to become pregnant or initiate breastfeeding during the study or within 1 month of the last dose of pirtobrutinib or 12 months of the last dose of rituximab. Patients unable to take oral medication or with clinically significant active malabsorption syndrome or other condition likely to affect gastrointestinal absorption of the study drug. Presence of B symptoms or any relevant symptoms related to the MCL. Nodal clinical forms with lymph node enlargement > 3 cm (largest diameter). Organ dysfunction related to MCL including creatinine level > 2 mg/dl or altered liver biochemistry (> 3x ULN). Serum LDH over ULN Known central nervous system (CNS) infiltration. Expected MCL therapy requirement in a short time (< 3 months) Anticoagulation requirement with vitamin K antagonists

Calendar

(Last Update: 04/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
24/06/2025	29/09/2025	30/09/2025	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

Fundacion Geltamo Spain

Avenida Valdecilla Sn

Contact Person

Ana María Méndez

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Monetary support: N/A

Sponsor type: Commercial

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Sites

Active (29/09/2025)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

Active (29/09/2025)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Active (29/09/2025)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Active (01/10/2025)

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Hematology

Active (29/10/2025)

Hospital Costa Del Sol

Marbella

MÁLAGA

Hematology

Active (24/11/2025)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology

Active (20/02/2026)

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Hematology

Active (30/10/2025)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Active (29/09/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Active (29/09/2025)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

Active (16/01/2026)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

Active (06/10/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Active (18/12/2025)

ICO L'HOSPITALET HOSPITAL DURAN I REYNALS

Barcelona

BARCELONA

Hematology

Active (07/10/2025)

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematology

Medication

MabThera 100 mg concentrate for solution for infusion

SOLUTION FOR INFUSION

INTRAVENOUS INFUSION

ATC code: L01FA01 - RITUXIMAB

Active Principles: N/A

Experimental

Jaypirca 100 mg film-coated tablets

FILM-COATED TABLET

ORAL

-

Active Principles: N/A

Experimental

MabThera 500 mg concentrate for solution for infusion

SOLUTION FOR INFUSION

INTRAVENOUS INFUSION

ATC code: L01FA01 - RITUXIMAB

Active Principles: N/A

Experimental

No results