Estudio de investigación para evaluar la eficacia de Concizumab en pacientes con hemofilia sin inhibidores

Estado	**Tipo de Participantes**	**Rangos de Edad**
Interrumpido	No aportado	Mayores de 64 , Adultos (18-64 años) , Adolescentes (12-17 años)
Género	**Fases**	**Participantes esperados**
Hombres	Fase III	115
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	NO

Información

Identificador

2023-506831-13-00 (CTIS)

Cod. Protocolo

NN7415-4307

Transicionado 2018-004891-36

Área terapéutica

Enfermedades [C] - Anormalidades congénitas, hereditarias y neonatología [C16]|

Enfermedad investigada

hemofilia A (HA) sin inhibidores y hemofilia B (HB) sin inhibidores

Título Científico

Eficacia y seguridad de la administración de Concizumab en profilaxis en pacientes con hemofilia A o B sin inhibidores

Justificación

No aportado

Objetivo Principal

Comparar el efecto de la profilaxis con concizumab con el de la ausencia de profilaxis (tratamiento a demanda con un factor) en la reducción del número de episodios hemorrágicos en pacientes adultos y adolescentes con hemofilia A sin inhibidores.
Comparar el efecto de la profilaxis con concizumab con el de la ausencia de profilaxis (tratamiento a demanda con un factor) en la reducción del número de episodios hemorrágicos en pacientes adultos y adolescentes con hemofilia B sin inhibidores.

Variables de Evaluación Primaria

Para pacientes con hemofilia A sin inhibidores: número de episodios hemorrágicos espontáneos y traumáticos tratados
A demanda (grupo 1)
Desde la aleatorización después de la pausa (semana 0) hasta el inicio del tratamiento con concizumab (semana 24)
Concizumab (grupo 2)
Desde el inicio de la nueva pauta posológica de concizumab (semana 0) hasta la fecha de corte de los análisis confirmatorios (al menos 32 semanas)
Para pacientes con hemofilia B sin inhibidores: número de episodios hemorrágicos espontáneos y traumáticos tratados.
A demanda (grupo 1)
Desde la aleatorización después de la pausa (semana 0) hasta el inicio del tratamiento con concizumab (semana 24)
Concizumab (grupo 2)
Desde el inicio de la nueva pauta posológica de concizumab (semana 0) hasta la fecha de corte de los análisis confirmatorios (al menos 32 semanas

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Comparar el efecto de la profilaxis con concizumab con el del tratamiento profiláctico previo del paciente en la reducción del número de episodios hemorrágicos en pacientes adultos y adolescentes con hemofilia A sin inhibidores.
Comparar el efecto de la profilaxis con concizumab con el del tratamiento profiláctico previo del paciente en la reducción del número de episodios hemorrágicos en pacientes adultos y adolescentes con hemofilia B sin inhibidores
Investigar la seguridad de la profilaxis con concizumab en pacientes adultos y adolescentes con hemofilia A o B sin inhibidores
Investigar los parámetros FC y FD de la profilaxis con concizumab en pacientes adultos y adolescentes con

hemofilia A o B sin inhibidore

Variables de Evaluación Secundaria

For haemophilia A patients without inhibitors: The number of treated spontaneous and traumatic bleeding episodes Arm 4 patients who have been on stable PPX at least 24 weeks in study 4322 For previous PPX (study 4322): From the point in time where PPX is stable and up until the end of study. For concizumab PPX (trial 4307): From the point in time where the concizumab maintenance dose is confirmed, increased or decreased and up until the confirmatory analyses cut-off (at least 24 weeks).
For haemophilia B patients without inhibitors: The number of treated spontaneous and traumatic bleeding episodes Arm 4 patients who have been on stable PPX at least 24 weeks in study 4322 For previous PPX (study 4322): From the point in time where PPX is stable and up until the end of study. For concizumab PPX (trial 4307): From the point in time where the concizumab maintenance dose is confirmed, increased or decreased and up until the confirmatory analyses cut-off (at least 24 weeks).
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Number of thromboembolic events On demand (arm 1 main part) From randomisation to on demand treatment until start of concizumab treatment Concizumab (arms 2-4) Before the pause: From start of concizumab treatment up until 7 weeks after the treatment was paused and After the pause: From start of concizumab treatment up until the confirmatory analyses cut-off (at least 32 weeks) Concizumab (arm 1 extension part) From start of concizumab treatment up until the confirmatory analysis cut-off
Number of thromboembolic events Concizumab Before the pause: From start of treatment (week 0) up until 7 weeks after the treatment was paused as well as After the pause: From start of concizumab treatment up until the end of trial (up to 384 weeks)
Number of hypersensitivity type reactions On demand (arm 1 main part) From randomisation to on demand treatment up until start of concizumab treatment Concizumab (arms 2-4) Before the pause: From start of concizumab treatment up until 7 weeks after the treatment was paused and After the pause: From start of concizumab treatment up until the confirmatory analyses cut-off (at least 32 weeks) Concizumab (arm 1 extension) From start of concizumab treatment up until the confirmatory analysis cut-off
Number of hypersensitivity type reactions Concizumab Before the pause: From start of treatment (week 0) up until 7 weeks after the treatment was paused as well as After the pause: From start of concizumab treatment up until the end of trial (up to 384 weeks)

Number of injection site reactions On demand (arm 1 main part) From randomisation to on demand treatment until start of concizumab treatment Concizumab (arms 2-4) Before the pause: From start of concizumab treatment up until 7 weeks after the treatment was paused and After the pause: From start of concizumab treatment up until the confirmatory analyses cut-off (at least 32 weeks) Concizumab (arm 1 extension part) From start of concizumab treatment up until the confirmatory analysis cut-off
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Pre-dose (trough) concizumab plasma concentration (Ctrough) prior to the concizumab administration at week 24 (after restart)
Pre-dose thrombin peak prior to the concizumab administration at week 24 (after restart)
Pre-dose free TFPI concentration prior to the concizumab administration at week 24 (after restart)
Maximum concizumab plasma concentration (Cmax) from 0 to 24 hours where 0 is time of the concizumab dose at week 24 (after restart)
Area under the concizumab plasma concentration-time curve (AUC) from 0 to 24 hours where 0 is time of the concizumab dose at week 24 (after restart)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Obtención del consentimiento informado antes de cualquier actividad relacionada con el ensayo. Las actividades relacionadas con el ensayo son cualquier procedimiento llevado a cabo como parte del ensayo, entre ellas las actividades para determinar la elegibilidad para participar en el ensayo Hombres ¿12 años en el momento de la firma del consentimiento informado. Peso corporal >25 kg en la selección Hemofilia A congénita grave (FVIII <1 %) o B moderada/grave (FIX ¿2 %). Tratamiento documentado con un producto que contenga factor de coagulación en las últimas 24 semanas (no aplicable a los pacientes de NN7415-4255 (explorer5) incluidos antes de pausar el tratamiento

Criterios de Exclusión

Hipersensibilidad conocida o sospechada a cualquier componente del medicamento del ensayo o productos relacionados. Afección inflamatoria sistémica ya conocida, que requiere tratamiento sistémico en la selección Tratamiento con emicizumab en los 180 días anteriores a la selección Presencia confirmada de inhibidor ¿0,6 UB en la selección. Antecedentes conocidos de inhibidores ¿0,6 UB en los últimos 5 años de acuerdo con la historia clínica. Cualquier trastorno, excepto afecciones asociadas a la hemofilia, que en opinión del investigador pueda poner en peligro la seguridad del paciente o su cumplimiento del protocolo Participación previa en este ensayo. La participación se define como el consentimiento informado firmado. Sin embargo, esto no se aplica a los pacientes que fueron fallo de selección a decisión del promotor debido a la pausa en el tratamiento. Participación en cualquier ensayo clínico de un medicamento en investigación aprobado o no aprobado en el plazo de 5 semividas o 30 días

desde la selección, lo que sea más largo (no aplicable para los pacientes de NN7415-4255 incluidos antes de la pausa del tratamiento). Plaquetas ¿100 x 109/l en la selección Fibrinógeno por debajo del límite inferior normal de laboratorio en la selección. Disfunción hepática definida como AST y/o ALT >3 veces el límite superior, en combinación con un valor de bilirrubina total >1,5 veces el límite superior, en la selección. Insuficiencia renal definida como tasa de filtración glomerular estimada (TFGe) ¿30 ml/min/1,73 m2 para la creatinina sérica medida en la selección. Trastorno de coagulación hereditario o adquirido conocido y distinto de la hemofilia congénita. Antecedentes de enfermedad tromboembólica. Signos clínicos actuales de enfermedad tromboembólica o tratamiento para esta. Pacientes que, a criterio del investigador, se consideran en alto riesgo de acontecimientos tromboembólico

Calendario

(Última actualización: 04/08/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
19/09/2019	15/01/2020	11/02/2020	16/03/2020	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
03/12/2020	No aportado	No aportado	No aportado	No aportado

Promotor

Novo Nordisk A/S Denmark

Novo Alle 1

Contact Person

EU Submission Hub

+4544448888

EUSUBHUB@novonordisk.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitario La Paz

Paseo de la Castellana, 261 28046 Madrid

ceic.hulp@salud.madrid.org

917277413

Centros

Activo (17/02/2020)

HOSPITAL UNIVERSITARIO LA PAZ

Madrid

MADRID

Unidad de Coagulopatías - Servicio de Hematología

Activo (15/01/2020)

HOSPITAL UNIVERSITARIO REGIONAL DE MÁLAGA

Málaga

MÁLAGA

Servicio de Hematología y Hemoterapia

Activo (03/03/2020)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO

Sevilla

SEVILLA

UGS Hematología

Medicamentos

Concizumab C 40 mg/mL PDS290
SOLUTION FOR INJECTION
SUBCUTANEOUS

-

Principios Activos: N/A

Experimental

Concizumab C 100 mg/mL PDS290
SOLUTION FOR INJECTION
SUBCUTANEOUS

-

Principios Activos: N/A

Experimental

Sin resultados

Research study to look at how well the drug Concizumab works in your body if you have haemophilia without inhibitors

State	Type of participants	Age Ranges
Halted	Not provided	Older than 64 , Adults (18-64 years) , Teens (12-17 years)
Gender	**Phases**	**Expected Participants**
Men	Phase III	115
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness	NO

Information

Identifier
2023-506831-13-00 (CTIS)

Protocol Code
NN7415-4307

Transitioned 2018-004891-36

Therapeutic area
Diseases [C] - Congenital, Hereditary, and Neonatal Diseases and Abnormalities [C16]|

Investigated Disease
haemophilia A (HA) without inhibitors and haemophilia B (HB) without inhibitors

Scientific Title
Efficacy and Safety of Concizumab prophylaxis in patients with haemophilia A or B without inhibitors

Rationale

Not provided

Main Objective

To compare the effect of concizumab prophylaxis to no prophylaxis (on demand treatment with factor) in reducing the number of bleeding episodes in adult and adolescent patients with haemophilia A without inhibitors.
To compare the effect of concizumab prophylaxis to no prophylaxis (on demand treatment with factor) in reducing the number of bleeding episodes in adult and adolescent patients with haemophilia B without inhibitors.

Primary Endpoints

For haemophilia A patients without inhibitors: the number of treated spontaneous and traumatic bleeding episodes On demand (arm 1) From randomisation after the pause (week 0) up until start of concizumab treatment (week 24) Concizumab (arm 2) From start of the new concizumab dosing regimen (week 0) up until the confirmatory analyses cut-off (at least 32 weeks)
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Temporary moments of secondary assessment

Not provided

Secondary Objective

To compare the effect of concizumab prophylaxis to the patients previous prophylaxis treatment in reducing the number of bleeding episodes in adult and adolescent patients with haemophilia A without inhibitors
To compare the effect of concizumab prophylaxis to the patients previous prophylaxis treatment in reducing the number of bleeding episodes in adult and adolescent patients with haemophilia B without inhibitors
To investigate the safety of concizumab prophylaxis in adult and adolescent patients with haemophilia A or B without inhibitors
To investigate the PK and PD parameters of concizumab prophylaxis in adult and adolescent patients with haemophilia A or B without inhibitors

Secondary Endpoints

For haemophilia A patients without inhibitors: The number of treated spontaneous and traumatic bleeding episodes Arm 4 patients who have been on stable PPX at least 24 weeks in study 4322 For previous PPX (study 4322): From the point in time where PPX is stable and up until the end of study. For concizumab PPX (trial 4307): From the point in time where the concizumab maintenance dose is confirmed, increased or decreased and up until the confirmatory analyses cut-off (at least 24 weeks).

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(arm 1 extension part) From start of concizumab treatment (visit 9a) up until the confirmatory analysis cut-off
Number of patients with antibodies to concizumab Concizumab Before the pause: From start of treatment (week 0) up until 7 weeks after the treatment was paused as well as After the pause: From start of concizumab treatment up until the end of trial (up to 384 weeks)
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Pre-dose thrombin peak prior to the concizumab administration at week 24 (after restart)
Pre-dose free TFPI concentration prior to the concizumab administration at week 24 (after restart)
Maximum concizumab plasma concentration (Cmax) from 0 to 24 hours where 0 is time of the concizumab dose at week 24 (after restart)
Area under the concizumab plasma concentration-time curve (AUC) from 0 to 24 hours where 0 is time of the concizumab dose at week 24 (after restart)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Informed consent obtained before any trial-related activities. Trial-related activities are any procedures that are carried out as part of the trial, including activities to determine suitability for the trial Male aged 12 years at the time of signing informed consent Body weight >25 kg at screening Congenital severe haemophilia A (FVIII < 1%) or moderate/severe B (FIX 2%). Documented treatment with coagulation factor containing product in the last 24 weeks (not applicable for NN7415-4255 (explorer5) patients enrolled prior to the treatment pause).

Exclusion criteria

Known or suspected hypersensitivity to any constituent of the trial product or related products A known systemic inflammatory condition requiring systemic treatment at screening Treatment with emicizumab within 180 days before screening Presence of confirmed inhibitor 0.6 BU at screening Known history of inhibitors 0.6 BU in the last 5 years according to the medical records. Any disorder, except for conditions associated with haemophilia, which in the investigators opinion might jeopardise patients safety or compliance with the protocol Previous participation in this trial. Participation is defined as signed informed consent. However, this is not applicable for patients who were screen failed at Sponsors decision due to the treatment pause Participation in any clinical trial of an approved or non-approved investigational medicinal product within 5 half-lives or 30 days from screening, whichever is longer (not applicable for NN7415-4255 patients enrolled prior to the treatment pause). Platelets 100x109/L at screening Fibrinogen below laboratory lower normal limit at screening Hepatic dysfunction defined as AST and/or ALT >3 times the upper limit combined with total bilirubin > 1,5 times the upper limit at screening Renal impairment defined as estimated Glomerular Filtration Rate (eGFR) 30 ml/min/1.73 m2 for serum creatinine measured at screening Known inherited or acquired coagulation disorder other than congenital haemophilia History of thromboembolic disease. Current clinical signs of, or treatment for thromboembolic disease. Patients who in the judgement of the investigator are considered at high risk of thromboembolic events

Calendar

(Last Update: 04/08/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
19/09/2019	15/01/2020	11/02/2020	16/03/2020	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
03/12/2020	Not aported	Not aported	Not aported	Not aported

Sponsor

Novo Nordisk A/S Denmark

Novo Alle 1

Contact Person

EU Submission Hub

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EUSUBHUB@novonordisk.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

Active (17/02/2020)

HOSPITAL UNIVERSITARIO LA PAZ

Madrid

MADRID

Unidad de Coagulopatías - Servicio de Hematología

Active (15/01/2020)

HOSPITAL UNIVERSITARIO REGIONAL DE MÁLAGA

Málaga

MÁLAGA

Servicio de Hematología y Hemoterapia

Active (03/03/2020)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO

Sevilla

SEVILLA

UGS Hematología

Medication

Concizumab C 40 mg/mL PDS290

SOLUTION FOR INJECTION

SUBCUTANEOUS

-

Active Principles: N/A

Experimental

Concizumab C 100 mg/mL PDS290

SOLUTION FOR INJECTION

SUBCUTANEOUS

-

Active Principles: N/A

Experimental

No results