Therapy with obinutuzumab for patients with lymphoma

Gepubliceerd: 23-03-2015 Laatst bijgewerkt: 19-03-2025

Obinutuzumab can provide clinical benefit in patients with rituximab-refractory follicular lymphoma

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24035

Bron
NTR

Verkorte titel
Zr-Obi

Aandoening

rituximab-refractory follicular lymphoma
in Dutch: rituximab-refractair folliculair lymfoom

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: Roche

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• Overall response rate using the Revised Response Criteria for Malignant Lymphoma (RRMCML) for disease assessment.

Toelichting onderzoek

Achtergrond van het onderzoek

Double registration. See NL4816 (old NTR5317) for up-to-date information.

Doel van het onderzoek

Obinutuzumab can provide clinical benefit in patients with rituximab-refractory follicular lymphoma

Onderzoeksopzet

Response evaluation at week10-12 with FDG-PET/CT

Onderzoeksproduct en/of interventie

obinutuzumab monotherapy given as 4 weekly infusions

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Biopsy-proven rituximab refractory follicular lymphoma (defined as disease progression while on rituximab maintenance therapy). Patients are required to have received a minimum of 2 infusions of rituximab maintenance therapy and/or be on a maintenance schedule for a minimum of 3 months (measured from the time of first maintenance infusion). Disease progression must have occurred before the last maintenance infusion.

• No clinical or pathological evidence of transformation to high-grade or diffuse large B-cell lymphoma (e.g. B symptoms, fast-growing tumour, or increasing lactate dehydrogenase level)

• Patients must have radiographically documented measurable disease, defined as 2 or more clearly demarcated lesions with a largest diameter of at least 1.5 cm or 1 clearly demarcated lesion with a largest diameter of at least 2.0 cm by computed tomography scan. All radiology studies must be performed within 14 days prior to registration.

• Adult patients, >=18 years of age

• Clinical indication for treatment as determined by the “treating physician”

• ECOG performance status of 0, 1 or 2.

• Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial

• Before patient registration, written informed consent must be given according to GCP, and national regulations.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Known central nervous system involvement

• Concurrent use of other anti-cancer agents

• All other lymphoma treatment (except rituximab maintenance therapy) during the last 6 months.

• Concurrent use of glucocorticoids (>10mg/day prednisolone or equivalent), or glucocorticoids (>10mg/day prednisolone or equivalent) within 4 weeks of first infusion

• Prior use of any investigational monoclonal antibody within 6 months of study start

• Prior use of any anti-cancer vaccine

• Previous allogeneic stem cell transplantation at any time or previous autologous stem cell transplantation within 6 months of first infusion

• More than 1 previous radioimmunotherapy

• Radioimmunotherapy within 3 months of first infusion

• Other active malignancy or history of other active malignancy. However patients who have been free of malignancy for at least 5 years, or have a history of completely resected non-melanoma skin cancer, or successfully treated in situ carcinoma are eligible.

• Intolerance of exogenous protein administration

• Pregnant and breastfeeding women and those of childbearing potential who are not able or willing to use adequate and effective contraception.

Definition of adequate and effective contraception: use of two reliable forms of contraception.

For women, effective contraception is required to continue for ≥ 12 months after the last dose of obinutuzumab. For men, effective contraception is required to continue for ≥ 3 months after the last dose of obinutuzumab.

• Life expectancy < (less than) 6 months

• Clinical significant cardiovascular disease, such as New York Heart Association Class III or IV cardiac disease, myocardial infarction within the last 6 months, unstable arrhythmias, or unstable angina)

• Active infectious disease, requiring systemic treatment:

o Positive test results for chronic hepatitis B virus (HBV) infection (defined as positive hepatitis B virus surface antigen [HBsAg] and/or hepatitis B core antibody [HBcAb] serology)

o Positive test results for hepatitis C (hepatitis C virus [HCV] antibody serology testing) Patients positive for HCV antibody are eligible only if polymerase chain reaction is negative for HCV RNA

o Vaccination with a live vaccine within 28 days prior to the start of study drug (Cycle 1, Day 1)

o Known HIV or HTLV-1 infection

• Any of the following abnormal laboratory values:

o Creatinine □□1.5 times the upper limit of normal (unless creatinine clearance normal), or creatinine clearance □□40 ml/min

o Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) □□2.5 times the upper limit of normal

o Total bilirubin □□□3 □□ULN

o Neutrophil count □□1.5 □□109/L (unless due to underlying disease, as established by extensive bone marrow involvement)

o Hemoglobin □□8 g/dL (unless due to underlying disease, as established by extensive bone marrow involvement)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2015
Aantal proefpersonen:	25
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	23-03-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41828
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4865
NTR-old	NTR5110
CCMO	NL48577.029.14
OMON	NL-OMON41828

Resultaten