Study of Cabozantinib (XL184) vs Placebo in Subjects With Hepatocellular Carcinoma Who Have Received Prior Sorafenib (CELESTIAL)

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Cabozantinib improves overall survival in patients with hepatocellular carcinoma compared with placebo

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23693

Bron
Nationaal Trial Register

Verkorte titel
CELESTIAL

Aandoening

Hepatocellular Carcinoma

Ondersteuning

Primaire sponsor: Exelixis
Overige ondersteuning: Exelixis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Overall survival

Toelichting onderzoek

Achtergrond van het onderzoek

This study is investigating a therapy called cabozantinib for the treatment of advanced hepatocellular carcinoma, the most common form of liver cancer, in adults whose disease has spread or grown after treatment with the medication sorafenib. The main purpose of the CELESTIAL trial is to determine whether cabozantinib can improve patient survival.

Doel van het onderzoek

Cabozantinib improves overall survival in patients with hepatocellular carcinoma compared with placebo

Onderzoeksopzet

Up to 38 months

Onderzoeksproduct en/of interventie

Cabozantinib

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

o Histological or cytological diagnosis of hepatocellular carcinoma

o The subject has disease that is not amenable to a curative treatment approach

o Received prior sorafenib

o Progression following at least 1 prior systemic treatment for hepatocellular carcinoma

o Recovery from adverse events patient may have experienced from prior therapies

o ECOG performance status of 0 or 1

o Adequate hematologic and renal function

o Child-Pugh Score of A

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

o Fibrolamellar carcinoma or mixed hepatocellular cholangiocarcinoma

o Receipt of more than 2 prior systemic therapies for advanced hepatocellular carcinoma

o Any type of anticancer agent (including investigational) within 2 weeks before randomization

o Radiation therapy within 4 weeks (2 weeks for radiation for bone metastases) or radionuclide treatment within 6 weeks of randomization

o Prior cabozantinib treatment

o Known brain metastases or cranial epidural disease unless adequately treated with radiotherapy and/or surgery and stable for at least 3 months before randomization

o Concomitant anticoagulation, at therapeutic doses, with anticoagulants

o Subjects with untreated or incompletely treated varices with bleeding or high risk for

bleeding

o Moderate or severe ascites

o Pregnant or lactating females

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	23-07-2013
Aantal proefpersonen:	760
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	03-04-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6180
NTR-old	NTR6335
Ander register	XL184-309 : NCT01908426

Resultaten