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

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23693

Source
Nationaal Trial Register

Brief title
CELESTIAL

Health condition

Hepatocellular Carcinoma

Sponsors and support

Primary sponsor: Exelixis
Source(s) of monetary or material Support: Exelixis

Intervention

Outcome measures

Primary outcome

Overall survival

Secondary outcome

Progression-free survival, objective response rate

Study description

Background summary

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.

Study objective

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

Study design

Up to 38 months

Intervention

Cabozantinib

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	23-07-2013
Enrollment:	760
Type:	Unknown

Ethics review

Positive opinion

Date:	03-04-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results