The efficacy of cabozantinib in advanced salivary gland cancer patients, a phase II clinical trial

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To assess the objective response rate (ORR), progression free survival (PFS), overall survival (OS), duration of response (DoR), toxicity, and quality of life (QoL) of patients with advanced SGC treated with cabozantinib in 3 cohorts: salivary duct...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metastases
Study type	Interventional

Summary

ID

NL-OMON46770

Source
ToetsingOnline

Brief title
Cabo ASAP

Condition

- Metastases

Synonym
salivary gland cancer

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ipsen Pharma,Ipsen Pharmaceuticals

Intervention

Keyword: adenoid cystic carcinoma, cabozantinib, salivary duct carcinoma, salivary gland cancer

Outcome measures

Primary outcome

To assess the objective response rate (ORR)

Secondary outcome

To assess the progression free survival (PFS), overall survival (OS), duration

of response (DoR), toxicity, and quality of life (QoL) of patients with

advanced SGC treated with cabozantinib in 3 cohorts: salivary duct carcinoma

(SDC), adenoid cystic carcinoma (ACC), other SGC*s.

Study description

Background summary

Salivary gland cancer (SGC) is a rare cancer with 24 histological subtypes. Treatment options for locally advanced and/or metastatic SGC are limited. The tyrosine kinase inhibitor cabozantinib suppresses tumor growth, angiogenesis, and metastasis, and has been approved for renal cell carcinoma and thyroid cancer. Cabozantinib may also be of value in advanced SGC because c-MET, one of the targets of cabozantinib, is frequently overexpressed in SGC.

Study objective

To assess the objective response rate (ORR), progression free survival (PFS), overall survival (OS), duration of response (DoR), toxicity, and quality of life (QoL) of patients with advanced SGC treated with cabozantinib in 3 cohorts: salivary duct carcinoma (SDC), adenoid cystic carcinoma (ACC), other SGC*s.

Study design

Single arm, single center, phase II clinical trial

Intervention

Cabozantinib tablets 60 mg once daily until progressive disease, intolerable toxicity, or investigator and/or patient decision to withdraw for a maximum duration of 2 years.

Study burden and risks

Burden and risks: Patients will use the study medication for a maximum duration of 2 years. During these 2 years, patients will make 17 study related visits with blood analysis, urine analysis and an ECG at every visit. 12 CT scans will be made and patients will be asked to fill in questionnaires 7 times. The safety of Cabometyx is well known because of studies in renal cell carcinoma.
Benefit: Because Cabometyx has not been tested in SGC patients before, the chance of responding to treatment is unknown. The Simon 2-stage design will be used to prevent exposure of too many patients to ineffective treatment without discarding a potential effective treatment because of treatment failure in some patients.
Group relatedness: The study does not involve minors and/or incapacitated subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a patient must meet all of the following criteria:
- Disease specific
- locally advanced, recurrent, and/or metastatic SGC (excluding sarcomas and mesenchymal tumors)
- c-MET positive disease (see paragraph 4.1)
- Measurable disease per RECIST version 1.1
- Cohort-specific criteria
- SDC cohort: Direct inclusion (no objective tumor growth prior to inclusion needed)
- ACC cohort: Inclusion after objective growth in the last three months or complaints due to the disease
- Other SGC*s: Inclusion after objective growth in the last three months or complaints due to the disease
- General conditions
- Age *18 years
- Eastern Cooperative Oncology Group performance status of 0 or 1.
- Normal number of neutrophils and thrombocytes
- Liver function: ALT and AST < 2.5 x upper limit of normal (ULN), Total bilirubin * 1.5 x ULN (except for Gilbert*s syndrome),
serum albumine *28 g/L
- Renal function: Creatinine < 1.5 x ULN or calculated creatinine clearance * 40 ml/min, Urine protein/creatinine ratio *113.1 mg/mmol (*1 mg/mg) or 24-hour urine protein <1 g
- Hemoglobin A1c (HbA1c) * 8% or a fasting serum glucose * 9 mmol/l

Exclusion criteria

- General conditions
- A known allergy for cabozantinib or its components
- Long QT-syndrome
- Pregnancy or lactation
- Patients (M/F) with reproductive potential not implementing adequate contraceptives measures
- Known brain metastases or cranial epidural disease unless adequately treated with radiotherapy and/or surgery and stable for at least
3 months before inclusion

- Major surgery within 3 months before randomization. Complete wound healing from major surgery must have occurred 1 month before
inclusion and from minor surgery at least 10 days before inclusion
- Uncontrolled illness including, but not limited to
- Cardiovascular disorders including symptomatic congestive heart failure, unstable angina pectoris, or serious cardiac arrhythmias
- Uncontrolled hypertension defined as sustained systolic BP > 150 mm Hg, or diastolic BP > 100 mm Hg
- Stroke (including TIA), myocardial infarction, or other ischemic event within 6 months before inclusion
- Serious active infections
- Concomitant treatments
- Concomitant (or within 4 weeks before inclusion) administration of any other experimental drug under investigation.
- Concurrent treatment with any other anti-cancer therapy.
- Concomitant anticoagulation.
- Low dose aspirin for cardioprotection and low dose LMWH are permitted.
- Radiation therapy within the last 4 weeks before inclusion

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-09-2018
Enrollment:	43
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	cabometyx
Generic name:	cabozantinib
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	16-05-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-07-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-08-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-12-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-05-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2018-000682-36-NL
CCMO	NL65109.091.18

Study results

Date completed: 06-11-2019

Actual enrolment: 25

Summary results
Trial is onging in other countries