An open label, multi-center, extension study to evaluate long-term safety and tolerability of dovitinib in patients with solid tumors, who continue to receive treatment with dovitinib (TKI258) in Novartis-sponsored, single agent dovitinib studies, which have fulfilled the requirements for the primary objective, and are benefitting from continued dovitinib treatment as assessed by the investigator

Published: 16-07-2014
Last updated: 21-04-2024

To collect long term data on safety and tolerability of dovitinib monotherapy.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON41205

Source
ToetsingOnline

Brief title
CTKI258A2X01B

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
solid tumors

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma BV

Intervention

Keyword: Dovitinib, Solid, TKI258, Tumors

Outcome measures

Primary outcome

Adverse events.

Secondary outcome

None.

Study description

Background summary

This is an extension study for subjects who have completed the study CTKI258A2120.
By joining the study subjects can continue treatment with dovitinib. In this study the long term effects of the drug dovitinib will be investigated. All subjects will be treated with active study drug.

Study objective

To collect long term data on safety and tolerability of dovitinib monotherapy.

Study design

Multicenter phase III non-comparative extension study. Continuation of the dovitinib dose from the previous study. Dose adjustment possible.
Treatment period until unacceptable side effects, withdrawal of consent or lack of benefit from treatment.
At least 25 patients.

Intervention

Treatment with dovitinib.

Study burden and risks

Risk: Adverse effects of study medication.
Burden: Visits every 4 weeks. Final visit 30 days post last dose of study treatment. All visits: physical examination, blood tests (approx. 10 ml blood), urine tests and ECG. At least every 16 weeks: tumor measurements. At start of study: MUGA-scan or echocardiogram.

Contacts

Public
Novartis

Raapopseweg 1
Arnhem 6824 DP
NL
Scientific
Novartis

Raapopseweg 1
Arnhem 6824 DP
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Patients with solid tumors, who are currently receiving treatment with single agent dovitinib within a Novartis study which has fulfilled the requirements for the primary objective.
* Patient is currently benefiting from the treatment with single agent dovitinib, as determined by the investigator.
* Patient has demonstrated compliance, as assessed by the investigator, with the parent study protocol requirements

Exclusion criteria

* Concurrent severe and/or uncontrolled concomitant medical conditions that could cause unacceptable safety risks or compromise compliance with the protocol
* Unresolved toxicities for which study drug dosing has been interrupted in the parent study.
* Pregnancy, lactation.
* Fertile males not willing to use safe contraception.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	1

Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Dovitinib
Generic name:	Dovitinib

Ethics review

Approved WMO Date:	16-07-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-07-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
Other	clinicaltrials.gov; registratienummer NCT02116803
EudraCT	EUCTR2014-000368-17-NL
CCMO	NL49595.031.14