

Study with S 81694 in perfusion in patients with solid tumors

Submission date 22/05/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/05/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration and not expected to be available in the future

Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2014-002023-10

ClinicalTrials.gov (NCT)
N/A

Protocol serial number
CL1-81694-001

Study information

Scientific Title

Phase I dose-escalation study of S 81694 administered intravenously in adult patients with advanced/metastatic solid tumors

Study objectives

To determine the maximum tolerated dose and the associated dose-limiting toxicities of S 81694

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Netherlands: Medisch Ethische Toetsings Commissie Erasmus MC, 07/10/2015, ref: NL51604.078.15.
2. Belgium: Commissie Medische Ethiek UZ Leuven and the Comité d'éthique Institut Bordet, 27/07/2015

Study design

Phase I multicentre open-label non-randomised non-comparative study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Advanced/metastatic solid tumors

Interventions

Vial containing 30 mg of powder for solution for infusion. From 12 mg/m² per cycle to the maximum tolerated dose. Intravenous use. Until disease progression or occurrence of unacceptable toxicity.

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

S 81694

Primary outcome(s)

Maximum tolerated dose and dose limiting toxicities from the day of the first dose administration in cycle 1 until the date of the first dose administration in cycle 2.

Key secondary outcome(s)

Current secondary outcome measures as of 19/03/2020:

1. Safety and tolerability profile of S 81694 from the informed consent signature to 30 days after the last treatment administration
2. Determination of the recommended phase II dose
3. Pharmacokinetics profile of S 81694 and its metabolite(s) in plasma and urine during cycle 1 and cycle 2

Previous secondary outcome measures:

1. Safety and tolerability profile of S 81694 from the informed consent signature to 30 days after the last treatment administration
2. Determination of the recommended phase II dose
3. Pharmacokinetics profile of S 81694 and its metabolite(s) in plasma and urine during cycle 1

Completion date

03/07/2019

Eligibility

Key inclusion criteria

1. Male or female patients with age \geq 18 years
2. Histologically or cytologically confirmed diagnosis of advanced/metastatic solid tumour in patients for whom no effective standard therapy is available or suitable
3. Elapsed time of 4 weeks or, in absence of toxicity, of 5 half-lives between the completion of the prior antineoplastic therapy including biologic, immunologic or targeted anticancer therapy and S 81694 first administration
4. Elapsed time of 6 weeks for nitrosoureas or mitomycin C
5. Resolution (return to baseline) or return to NCI CTCAE Grade \leq 1 of all acute toxicities due to prior anticancer therapy except alopecia, grade 2 paraesthesia, grade 2 hyper- or hypothyroidism and other non-clinically significant adverse events
6. ECOG (WHO) performance status 0-1
7. Patient must use effective contraception

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

39

Key exclusion criteria

1. Patients who have undergone treatment with high-dose chemotherapy requiring progenitor cell transplantation
2. Episode(s) of clinically relevant active bleeding in the past 3 weeks
3. Known history of haemolytic anaemia (including G6PD deficiency), thrombotic thrombocytopenic purpura (TTP), microangiopathic haemolytic anaemia (MAHA), haemolytic uremic syndrome(HUS)
4. Clinically significant respiratory or metabolic diseases uncontrolled by medication
5. Patients with uncontrolled high blood pressure
6. Presence of risk factors for torsade de pointes (e.g. heart failure, hypokalaemia, family history of long QT syndrome)

Date of first enrolment

05/10/2015

Date of final enrolment

07/01/2019

Locations

Countries of recruitment

Belgium

Netherlands

Study participating centre

Medical Oncology Clinic

Institut Jules Bordet

Université Libre de Bruxelles

Brussels

Belgium

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Study participating centre**Leuven Cancer Institute**

Department of General Medical Oncology

University Hospitals Leuven and Laboratory of Experimental Oncology

Department of Oncology

KU Leuven

Belgium

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Study participating centre**Erasmus MC Cancer Institute**

Netherlands

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Sponsor information

Organisation

Institut de Recherche Internationales Servier

ROR

<https://ror.org/034e7c066>

Funder(s)

Funder type

Industry

Funder Name

ADIR

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from <https://clinicaltrials.servier.com/> after the Marketing Authorisation has been granted.

Previous publication and dissemination plan:

We will comply with regulatory requirements

Summary results and a lay summary will be published on <https://clinicaltrials.servier.com/> within 12 months after the end of the study

IPD Sharing Plan:

The datasets generated during and/or analysed during the current study will be available upon request from <https://clinicaltrials.servier.com/> after the Marketing Authorisation has been granted.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/05/2022	16/05/2022	Yes	No
Basic results				No	No
Plain English results				No	Yes