ISRCTN35641359 https://doi.org/10.1186/ISRCTN35641359

Study with S 81694 in perfusion in patients with solid tumors

Submission date 22/05/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/06/2015	**Overall study status** Completed	
Last Edited 16/05/2022	**Condition category** Cancer	

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

Contact name
Dr Patrick Schöffski

Contact details
Department of General Medical Oncology
Leuven Cancer Institute
University Hospitals Leuven and Laboratory of Experimental Oncology
Department of Oncology
KU Leuven
Herestrat 49
Leuven
Belgium
B-3000

Type(s)
Public

Contact name
Mr Institut de Recherches Internationales Servier Clinical Studies Department

Contact details
50, rue Carnot
Suresnes
France

92284
00331 5572 4366
clinicaltrialmanagement@servier.com

Additional identifiers

EudraCT/CTIS number
2014-002023-10

IRAS number

ClinicalTrials.gov number
N/A

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
23/12/2014

Completion date
03/07/2019

Eligibility

Key inclusion criteria
1. Male or female patients with age ≥ 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 ≤ 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
72

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
-

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
-

Study participating centre
Erasmus MC Cancer Institute
Netherlands
-

Sponsor information

Organisation
Institut de Recherche Internationales Servier

Sponsor details
50, rue Carnot
Suresnes
France
92284

Sponsor type
Industry

Website
https://clinicaltrials.servier.com/

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
ADIR

Results and Publications

Publication and dissemination plan
Publication and dissemination plan as of 28/09/2018:
Summary results and a lay summary will be published on https://clinicaltrials.servier.com/ within 12 months after the end of the study

Intention to publish date
08/07/2020

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?
Basic results				No	No
Plain English results				No	Yes
Results article		11/05/2022	16/05/2022	Yes	No