ISRCTN85966108 https://doi.org/10.1186/ISRCTN85966108

Phase I study of S 78454 in combination with a fixed dose infusion of cisplatin in patients with advanced solid tumours

Submission date 04/10/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/12/2013	**Overall study status** Completed	
Last Edited 18/04/2018	**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

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Additional identifiers

Protocol serial number
CL1-78454-008

Study information

Scientific Title

Phase I dose-escalation study of oral administration of the Histone Deacetylase (HDAC) Inhibitor S 78454 given in combination with a fixed dose infusion of Cisplatin in patients with advanced solid tumours

Study objectives
To establish the safety profile and the recommended Phase II dose of S 78454 in combination with a fixed dose infusion of cisplatin

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethic approval was obtained before recruitment of the first participants

Study design
National multicentric non-randomised open-label dose escalation Phase I study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Advanced solid tumours

Interventions
1. Capsules containing 20 mg and 100 mg of S 78454 / Oral use / Treatment duration is at the discretion of the investigator
2. Fixed dose of i.v. infusion of cisplatin at 75 mg/m² / Cisplatin administration for up to 6 cycles, S 78454 could be maintained beyond

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
S 78454, cisplatin

Primary outcome(s)
1. DLTs and MTDs within the cycle 1 - Methods used: blood samples (biochemistry, haematology, coagulation analysis), physical examination and vital signs assessment, urinary analysis, ECG, clinical neurological examination, audiometric test
2. Safety profile of the combination at each visit

Key secondary outcome(s))

1. Pharmacokinetic evaluation on cycle 1 by blood sample
2. Circulating Tumour Cells measurements every 2 cycles by blood sample
3. Tumour response evaluation every 2 cycles according to RECIST criteria

Completion date
05/02/2014

Eligibility

Key inclusion criteria
1. Male or female patient aged > or equal to 18 years
2. Any histological confirmed diagnosis of advanced solid tumours that have relapsed or is refractory to conventional standard forms of therapy
3. Ability to swallow oral capsule(s)
4. Estimated life expectancy > 12 weeks
5. ECOG performance status < or equal to 1
6. Adequate haematological, renal and hepatic functions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Major surgery within previous 4 weeks
2. Chemotherapy within previous 3 weeks (6 weeks for nitroso-ureas)
3. Hormonotherapy within 2 weeks (6 weeks for bicalutamide)
4. Any other prior therapy directed at the solid tumours within 3 weeks
5. Radiotherapy within previous 4 weeks (except for palliative radiotherapy at localised lesions)
6. Cumulative radiation therapy involving > 25 % of total bone marrow
7. Pregnant or breast-feeding women, women of childbearing potential or men without effective contraception
8. Peripheral Neuropathy > grade 1
9. Hearing impairment/tinnitus > grade 2
10. Prior treatment with cisplatin reaching a cumulative dose of 300 mg/m²
11. Concomitant uncontrolled infection or severe systemic disease
12. Symptomatic or progressive brain metastasis
13. Patients with pre-existing gastrointestinal disorders
14. Concurrent therapeutic anticoagulation by AVK

15. Patient with impaired cardiac function
16. Patients with pre-existing gastro-intestinal disorders
17. Uncontrolled diabetes mellitus

Date of first enrolment
05/04/2012

Date of final enrolment
05/02/2014

Locations

Countries of recruitment
France

Study participating centre
Institut Paoli Calmettes
Marseille Cedex 9
France
13273

Sponsor information

Organisation
Institut de Recherches Internationales Servier (France)

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Institut de Recherches Internationales Servier (France)

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 if a Marketing Authorisation has been granted after 1st January 2014.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No