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AT9283 in children and adolescents with acute leukaemia

Submission date	Recruitment status	[_] Prospectively registered
31/10/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/10/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/10/2022	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-at9283-for-children-and-young-people-with-acute-leukaemia

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01431664

Clinical Trials Information System (CTIS)
2009-016952-36

Protocol serial number

11214

Study information

Scientific Title
A Cancer Research UK Phase I trial of AT9283 (a selective inhibitor of aurora kinases) given over 72 hours every 21 days via intravenous infusion in children and adolescents aged 6 months to 18 years with relapsed and refractory acute leukaemia

Study objectives
An open label, multi-centre, phase I dose escalation study of the aurora kinase inhibitor AT9283 in paediatric patients with relapsed and refractory acute leukaemia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Derby Medical Research Ethics Committee, 08/11/2010, ref: 10/H0405/75

Study design
Non-randomised interventional treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute Leukaemia

Interventions
Blood and tissue sampling, as per protocol schedule for the purposes of safety, disease assessment, pharmacokinetic and pharmacodynamic analysis. Disease assessment, According to the reposne criteria defined in the protocol; Treatment with AT9283, 72 hour infusion every 21 days.

Intervention Type
Other

Phase
Phase I

Primary outcome(s)
Identification of a dose of AT9283 for Phase II evaluation at end of study

Key secondary outcome(s))
1. Assessing AT9283 target kinase inhibition through pharmacodynamic analysis at end of study
2. Determining safety and tolerability of AT9283 throughout study conduct
3. Documenting evidence of activity of AT9283 by disease response assessment throughout

study conduct
4. Identifying predictive molecular markers through pharmacodynamic analysis at end of study
5. Investigating the PK profile of AT9283 in paediatric patients at end of study

Completion date
01/10/2014

Eligibility

Key inclusion criteria
1. Morhologically proven acute lymphoblastic or acute myeloid leukaemia
2. Life expectancy of at least 8 weeks
3. Karnofsky / Lansky scale score of > or = to 50%
4. Biochemical indices within ranges as specified in the protocol
5. Aged > 6 months to <19 years
6. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 months

Upper age limit
19 years

Sex
All

Total final enrolment
7

Key exclusion criteria
1. Chronic myeloid leukaemia
2. Cytotoxics, vincristine, anti-neoplastics within two weeks. One week for investigational medicinal products (except antibodies, for which a four week window must be observed), one week for protein kinase inhibitors and Intrathecal therapy before treatment
3. Central nervous system (CNS) disease
4. Ongoing toxic manifestations of previous treatments
5. Prior exposure to an aurora kinase inhibitor
6. Pregnant or lactating women
7. Fractional shortening of =29% on Echocardiogram
8. Previous anthracycline treatment with a cumulative dose equal to or greater than 450mg/m2 doxorubicin equivalent

9. Uncontrolled arterial hypertension defined as a systolic and / or diastolic blood pressure greater than or equal to the 95th percentile for age and height
10. Congenital heart disease, with the exception of patent foramen ovale or small muscular ventricular septal deficit (within the first year of life)
11. Active graft vs. host disease
12. Patients experiencing significant toxicity following Haematopoietic Stem Cell Transplant.

Date of first enrolment
14/09/2011

Date of final enrolment
01/10/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cancer Research UK
London
United Kingdom
EC1V 4AD

Sponsor information

Organisation
Cancer Research UK

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research (UK)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
HRA research summary			28/06/2023	No	No
Plain English results			26/10/2022	No	Yes