

# AT9283 in children and adolescents with acute leukaemia

<b>Submission date</b> 31/10/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/10/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/10/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2009-016952-36

### ClinicalTrials.gov (NCT)

NCT01431664

### Protocol serial number

## 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 response 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. Morphologically 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  $\leq 29\%$  on Echocardiogram
8. Previous anthracycline treatment with a cumulative dose equal to or greater than 450mg/m<sup>2</sup> 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?
<a href="#">Basic results</a>				No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Plain English results</a>			26/10/2022	No	Yes