

A randomised, parallel group study on efficacy and tolerability of Escherichia coli rHu granulocyte-macrophage colony-stimulating factor (GM-CSF) given subcutaneously for seven days after chemotherapy in paediatric malignancy

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 21/01/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

Protocol serial number
NAG9007

Study information

Scientific Title

A randomised, parallel group study on efficacy and tolerability of Escherichia coli rHu granulocyte-macrophage colony-stimulating factor (GM-CSF) given subcutaneously for seven days after chemotherapy in paediatric malignancy

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chemotherapy in paediatric malignancy

Interventions

1. GM-CSF regimen: myelosuppressive chemotherapy followed by Escherichia coli rHu GM-CSF given subcutaneously for seven days
2. Control regimen: myelosuppressive chemotherapy

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Escherichia coli rHu and granulocyte-macrophage colony-stimulating factor (GM-CSF)

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/11/1993

Eligibility

Key inclusion criteria

1. Newly diagnosed soft tissue sarcoma, Ewing's sarcoma, medulloblastoma, osteosarcoma or Non-Hodgkin's Lymphoma
2. Age range 1 to 15 years
3. No history of anaphylaxis
4. No severe lung, heart or kidney impairment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

1 years

Upper age limit

15 years

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1993

Date of final enrolment

30/11/1993

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation

United Kingdom Children's Cancer Study Group (UK)

Funder(s)

Funder type

Research organisation

Funder Name

United Kingdom Children's Cancer Study Group (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes