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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	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 21/01/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1993

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

Age group
Child

Lower age limit
1 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
United Kingdom Children's Cancer Study Group (UK)

Sponsor details
University of Leicester
3rd floor
Hearts of Oak House
9 Princess Road West
Leicester
United Kingdom
LE1 6HT

Sponsor type
Research organisation

Website
http://www.ukccsg.org

Funder(s)

Funder type
Research organisation

Funder Name
United Kingdom Children's Cancer Study Group (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration