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A comparison of hybrid chemotherapy versus hybrid chemotherapy and autotransplant in poor prognosis Hodgkin's disease

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 13/06/2014	**Condition category** Cancer	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SNLG HDIII

Study information

Scientific Title

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
Lymphoma (Hodgkin's)

Interventions
All patients receive three 28-day cycles of PVACE-BOP (chlorambucil, procarbazine, etoposide, vinblastine, adriamycin, bleomycin and prednisolone), together with co-trimoxazole every 3 weeks for the duration of treatment.

Patients who achieve at least a partial remission are randomised to one of two treatment regimens:
1. Regimen A: Radiotherapy, 30 Gy in 3 weeks to initially bulky sites or residual areas of disease, followed by two further cycles of PVACE-BOP
2. Regimen B: Radiotherapy, 30 Gy in 3 weeks to initially bulky sites or residual areas of disease, followed by intensive chemotherapy with melphan and etoposide plus autologous bone marrow transplantation.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2001

Completion date
31/12/2004

Eligibility

Key inclusion criteria
1. Histological diagnosis of Hodgkin's disease
2. Prognostic index of at least 0.5
3. Aged under 60
4. No prior chemotherapy or radiotherapy
5. No known significant heart, lung or renal disease
6. No co-existing malignancies apart from localised skin lesions

Participant type(s)
Patient

Age group
Adult

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
01/01/2001

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
UK Co-ordinating Committee for Cancer Research (UKCCCR)

Sponsor details
MRC Clinical Trials Unit
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Sponsor type
Government

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2002		Yes	No