ISRCTN99811594 https://doi.org/10.1186/ISRCTN99811594

The role of FluoroDeoxyGlucose-Positron Emission Tomography imaging in clinical stages Ia/IIa Hodgkin's disease

Submission date 20/10/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/10/2003	**Overall study status** Completed	
Last Edited 26/10/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-using-pet-scans-to-help-decide-treatment-options-for-early-stage-hodgkins-lymphoma

Contact information

Type(s)
Scientific

Contact name
Ms Bilyana Popova

Contact details
Cancer Research UK and UCL Cancer Trials Centre
90 Tottenham Court Road
London
United Kingdom
W1T 4TJ
-
fdg-pet@ctc.ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00943423

Secondary identifying numbers
LRF 02/20

Study information

Scientific Title
A randomised phase III trial to determine the role of FluoroDeoxyGlucose-Positron Emission Tomography imaging in clinical stages Ia/IIa Hodgkin's disease

Acronym
FDG-PET

Study objectives
Added 06/01/2009:
FluoroDeoxyGlucose-Positron Emission Tomography (FDG-PET) negativity after three cycles of adriamycin (doxorubicin), bleomycin, vinblastine and dacarbazine (ABVD) is indicative of a level of response whereby radiotherapy can be safely omitted without significantly compromising the duration of remission for patients with stage Ia/IIa Hodgkin's disease above the diaphragm.

On 05/01/2009 the following changes were made to this trial record:
1. The anticipated end date was changed from 01/10/2003 to 31/12/2009 (correction)
2. The target number of participants was changed from 320 to 400. An ethics approval has been obtained for this amendment.

Other changes are recorded within the relevant fields.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West Research Ethics Committee, 04/07/2003, ref: 03/8/056. An amendment to the number of participants was approved on 08/08/2008.

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
Hodgkin's Disease

Interventions
Patients with a negative PET scan after three cycles of ABVD treatment will be randomised to involved field radiotherapy or no further treatment.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Adriamycin (doxorubicin), bleomycin, vinblastine and dacarbazine (ABVD)

Primary outcome measure
Added 05/01/2009:
Three-year progression-free survival.

Secondary outcome measures
Added 05/01/2009:
1. Incidence of FDG-PET positivity/negativity after three cycles of ABVD
2. Survival (time from date of registration/randomisation to date of death from any cause) and cause of death. Participants will be followed up until death.
3. Incidence and type of second cancers. Participants will be followed up until death.

Overall study start date
01/10/2003

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Aged 16 - 75 years, either sex
2. Histologically confirmed Hodgkin's disease (histology will be reviewed retrospectively by Professor A Jack at the Haematological Malignancy Diagnostic Service in Leeds but please note that this is not required before trial entry)
3. Clinical stages Ia/IIa above the diaphragm with no mediastinal bulk (defined as maximum transverse diameter of mediastinal mass: internal thoracic diameter at level of D5/6 interspace greater than 0.33). Bulky disease at other sites (defined as nodal mass with transverse diameter greater than 10 cm) is acceptable.
4. No previous treatment for Hodgkin's disease
5. No previous malignancy excepting appropriately treated basal cell carcinoma of the skin or carcinoma in situ of the cervix

6. No contraindications to chemotherapy or radiotherapy
7. Patients with reproductive potential: a willingness to use contraception from entry into the study for a period of 6 months
8. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Total final enrolment
571

Key exclusion criteria
1. Patients with clinical stage Ia Hodgkin's disease with no clinical or computed tomography (CT) evidence of disease after diagnostic biopsy
2. Pregnant or lactating women
3. Severe underlying illness considered likely to make the trial therapy hazardous (for example severe heart disease or lung fibrosis)
4. Patients unwilling to travel to the nearest PET Centre
5. Patients unable to comply with follow-up arrangements

Date of first enrolment
01/10/2003

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cancer Research UK and UCL Cancer Trials Centre
London
United Kingdom
W1T 4TJ

Sponsor information

Organisation
Leukaemia Research Fund (UK)

Sponsor details
43 Great Ormond Street
London
United Kingdom
WC1N 3JJ
-
sgerscher@lrf.org.uk

Sponsor type
Charity

Website
http://www.lrf.org.uk

ROR
https://ror.org/0055acf80

Funder(s)

Funder type
Charity

Funder Name
Leukaemia Research Fund (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	23/04/2015	14/02/2020	Yes	No
Plain English results			26/10/2022	No	Yes