

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

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

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

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00943423

Protocol serial number

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/Ila 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/Ila 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.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Added 05/01/2009:

Three-year progression-free survival.

Key secondary outcome(s)

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.

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/Ila 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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

Cancer Research UK and UCL Cancer Trials Centre

London

United Kingdom

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Sponsor information**Organisation**

Leukaemia Research Fund (UK)

ROR

<https://ror.org/0055acf80>

Funder(s)**Funder type**

Charity

Funder Name

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