ISRCTN49014661 https://doi.org/10.1186/ISRCTN49014661

Chemotherapy with methotrexate and cytarabine with or without thiotepa, and with or without rituximab, followed by brain irradiation vs chemotherapy supported by autologous stem cells transplantation for immunocompetent patients with central nervous system lymphoma

Submission date 10/08/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/08/2011	**Overall study status** Completed	
Last Edited 25/10/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-high-dose-chemotherapy-radiotherapy-stem-cell-transplant-people-recently-diagnosed-primary-lymphoma-brain-spinal-cord-ielgs-32

Study website
http://www.ctu.soton.ac.uk/trial.aspx?trialid=31

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2009-012432-32

IRAS number

ClinicalTrials.gov number
NCT01011920

Secondary identifying numbers
10139

Study information

Scientific Title
Randomized phase II trial on primary chemotherapy with high-dose methotrexate and high-dose cytarabine with or without thiotepa, and with or without rituximab, followed by brain irradiation vs high-dose chemotherapy supported by autologous stem cells transplantation for immunocompetent patients with newly diagnosed primary CNS lymphoma.

Acronym
IELSG32

Study objectives
Objectives:
To establish in a prospective, randomized phase II trial, the activity of three different chemotherapy combinations in patients with newly diagnosed primary central nervous system lymphoma (PCNSL):
1. High-dose methotrexate (HD-MTX) + high-dose cytarabine (HD-araC)
2. HD-MTX + HD-araC + rituximab
3. HD-MTX + HD-araC + rituximab + thiotepa

To establish the efficacy of two consolidation strategies: conventional whole-brain radiotherapy (WBRT) vs. highdose chemotherapy supported by autologous stem cell transplantation (HDC + ASCT) in patients with newly diagnosed PCNSL.

Ethics approval required
Old ethics approval format

Ethics approval(s)
29/06/2011, ref: 11/LO/0420

Study design
Randomised, interventional

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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 (non-Hodgkin's)

Interventions
Patients will be randomised to one of 3 chemotherapy regimens:
Arm A Methotrexate & Cytarabine
Arm B - Methotrexate & Cytarabine with Rituximab
Arm C Methotrexate & Cytarabine with Rituximab and Thiotepa

Those who are in SD or respond to treatment will be further randomised to consolidation therapy.
Arm D Whole Brain Radiotherapy
Arm E BCNU, Thiotepa and Stem Cell Transplant

Follow Up Length: 120 month(s); Study Entry : Multiple Randomisations

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
1. Carmustine 2. Cytarabine 3. Methotrexate 4. Rituximab 5. Thiotepa

Primary outcome measure
Complete remission following primary chemotherapy

Secondary outcome measures
Failure-free survival at 2 years

Overall study start date
01/10/2011

Completion date

30/09/2013

Eligibility

Key inclusion criteria
1. Histological or cytological assessed diagnosis of non-Hodgkin's lymphoma
2. Diagnostic sample obtained by stereotactic or surgical biopsy, cerebrospinal fluid (CSF) cytology examination or vitrectomy
3. Disease exclusively localized into the central nervous system, CSF, cranial nerves or eyes
4. At least one measurable lesion
5. Previously untreated patients (previous or ongoing steroid therapy admitted)
6. Aged 18-65 years (with ECOG Performance Status 0-3), Aged 66-70 (with ECOG Performance Status 0-2)
7. Adequate bone marrow (PLT = 100000 mm3, Hb = 9 g/dl, ANC = 2.000 mm3)
8. Adequate bone marrow (PLT ≥100000 mm3, Hb ≥ 9 g/dl, ANC ≥ 2.000 mm3), renal (creatinine clearance ≥ 60 ml/min)
cardiac (VEF ≥ 50%), hepatic function (total serum bilirubin ≤ 3 mg/dL, AST/ALT and γGT ≤ 2 per upper normal limit value).
9. Sexually active patients of childbearing potential agreeing in implementing adequate contraceptive measures during study participation. (13 is part of 12 inclusion criteria)
10. Absence of any familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule
11. Patient-signed informed consent obtained before registration
12. Male or female participants

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 126

Total final enrolment
227

Key exclusion criteria
1. Patients with lymphomatous lesions outside the CNS
2. Patients with a previous non-Hodgkin lymphoma at any time
3. Previous or concurrent malignancies with the exception of surgically cured carcinoma in-situ

of the cervix, carcinoma of the skin or other cancers without evidence of disease at least from 5 years
4. Hepatitis-B-Virus surface antigen (HBsAg) and Hepatitis-C-Virus (HCV) positivity
5. HIV infection, previous organ transplantation or other clinically evident form of immunodeficiency
6.Concurrent treatment with other experimental drugs
7. Concurrent pregnancy or lactation
8. Patients not agreeing to take adequate contraceptive measures during the study
9. Symptomatic coronary artery disease, cardiac arrhythmias uncontrolled with medication or myocardial infarction within the last 6 months (New York Heart Association Class III or IV heart disease)

Date of first enrolment
01/10/2011

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
England

Germany

Italy

Switzerland

United Kingdom

Study participating centre
Clinical Trials Unit
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Southampton University Hospitals NHS Trust

Sponsor details
Tremona Road
Southampton
England

United Kingdom
SO16 6YD

Sponsor type
Hospital/treatment centre

Website
http://www.suht.nhs.uk/

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK Clinical Trials Advisory and Awards Committee

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	01/05/2016	10/04/2019	Yes	No
Results article	results	01/11/2017	10/04/2019	Yes	No
Plain English results			25/10/2022	No	Yes
HRA research summary			28/06/2023	No	No