A trial to investigate the efficacy and feasibility of treatment with dose adjusted EPOCH-R (DA-EPOCH-R), adapted to risk profile in patients with newly diagnosed Burkitt lymphoma.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26111

Source
Nationaal Trial Register

Brief title
DA-EPOCH-R trial

Health condition

Burkitt lymphoma, Burkitt Lymfoom

Sponsors and support

Primary sponsor: VU University Medical Center Amsterdam
Source(s) of monetary or material Support: sponsor

Intervention

Outcome measures

Primary outcome

1. 2 years overall survival (OS; time from registration. Patients still alive or lost to follow up are censored at the date they were last known to be alive) and progression free survival (PFS; i.e. time from registration to progression or death from any cause, whichever comes first);

2. Number of cycles of the DA-EPOCH-R scheme completed on an out-patient –clinic basis.

Secondary outcome

Negative predictive value of low dose PET/CT scan after 2 cycles of DA-EPOCH-R on OS and PFS.

Study description

Background summary

Study phase: Phase II.

Patient population:

Patients with newly diagnosed Burkitt lymphoma ≥ 18years.

Study objective:

To asses efficacy (PFS and OS at 2 years) and feasibility (defined as number of cyles administered on an out-patient-clinic basis) of risk-adapted DA-EPOCH-R in patients with newly diagnosed Burkitt lymphoma

Study design:

A prospective, monocenter, open label, non-randomized clinical trial:

1. Low risk patients will receive 3 cycles of DA-EPOCH-RR;

2. High risk patients will receive 6 cycles of DA-EPOCH-R;

3. CSF cytology will be done in all patients;

4. High Risk patients with CSF negative will receive prophylactic intrathecal treatment;

5. Low risk patients with CSF negative (1 normal LP and no clinical suspicion) will not receive prophylactic intrathecal treatment;

6. All patients with CSF positive will receive active intrathecal treatment;

7. FDG-PET/CT pre- and post-cycle 2 in all patients. Low risk patients with positive low-dose PET/CT (positive defined as a score ≥ 3 according to Deauville criteria (appendix B1) after 2 cycles will receive 6 cycles of DA-EPOCH-R;

8. A total of 22 patients will be enrolled in the protocol.

Study objective

The DA-EPOCH-R regimen represents a major paradigm shift for the treatment of BL. Whereas standard treatment relies on dose density and intensity based on methotrexate and cytarabin to achieve adequate cell kill, DA-EPOCH-R relies on a pharmacodynamic based infusional schedule to improve the therapeutic index of chemotherapy. Based on the pilot results presented by Dunleavy at ICML 2011, DA-EPOCH- R appears to provide a high rate of cure with significantly lower treatment toxicity and tumor lysis syndrome compared to standard treatment. As such, DA-EPOCH-R may provide a major treatment advance in BL by lowering morbidity, mortality, and cost, while maintaining or possibly improving efficacy. The current protocol is aims to confirm the results obtained with DA-EPOCH-R in BL in Dutch general hematology practice, as this protocol has been conducted primarily by the NIH.

Study design

Total expected study duration is 5 years.

Study start (FPFV): Nov 2012;

Recruitment end (LPFV): Nov 2015;

Study end (LPLV): Nov 2017;

Completion of Clinical Study Report (CSR): June 2018;

Publication date: June 2018.

Intervention

1. Low risk patients (3 cycles of Dose Adjusted EPOCH with 2xRituximab);

2. High risk patients (6 cycles of DA-EPOCH-Rituximab).

EPOCH is Etoposide, Prednisone, Vincristine, Cyclophosphamide, Doxorubicin.

Low risk patients with a positive PET-CTscan after 2 cycles of DA-EPOCH-RR will receive 4 cycles of DA-EPOCH-R.

Contacts

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Eligibility criteria

Inclusion criteria

1. First diagnosis of Burkitt lymphoma, histological confirmed according to the WHO classification 2008;

2. Age ≥ 18 years;

3. No prior treatment except local radiation or short course steroids ≤ 1 mg/kg for acute symptoms;

4. All disease stages;

5. HIV negative or positive;

6. ECOG-WHO status 0-3, status 4 only if disease related;

7. Written informed consent.

Exclusion criteria

1. All histopathological diagnoses other than BL according to the WHO classification 2008, irrespective of the presence of MYC rearrangement;

2. Inadequate renal function or creatinine clearance < 50 ml/min unless lymphoma related;

3. Inadequate hepatic function: bilirubin > 2 * ULN (total) except patients with Gilbert’s syndrome as defined by > 80% unconjugated;

4. Inadequate hematological function ANC < 1x109/l and platelets < 75x109 /l unless lymphoma related;

5. leukemic Burkitt lymphoma, defined as >30% blasts in bone-marrow and/or peripheral blood, without significant lympadenopathy;

6. Female subject of child-bearing potential not willing to use an acceptable method of birth control (i.e., a hormonal contraceptive, intra-uterine device, diaphragm with spermicide, condom with spermicide, or abstinence) for the duration of the study and one year beyond treatment completion;

7. Female subject pregnant or breast-feeding;

8. Male subject unwilling to use an acceptable method for contraception for the duration of the study and one year beyond treatment completion;

9. History of a prior invasive malignancy in past 5 years;

10. Active symptomatic ischemic heart disease, myocardial infarction, or congestive heart failure within the past year. If echo is obtained the LVEF should exceed 40%;

11. Serious concomitant medical illnesses that would jeopardize the patient's ability to receive the regimen with reasonable safety;

12. HIV positive patients not willing to suspend HAART therapy during the treatment period of the protocol.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2012
Enrollment:	22
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-12-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3585

Register	ID
NTR-old	NTR3750
Other	EudraCT : 2012-003141-16
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A