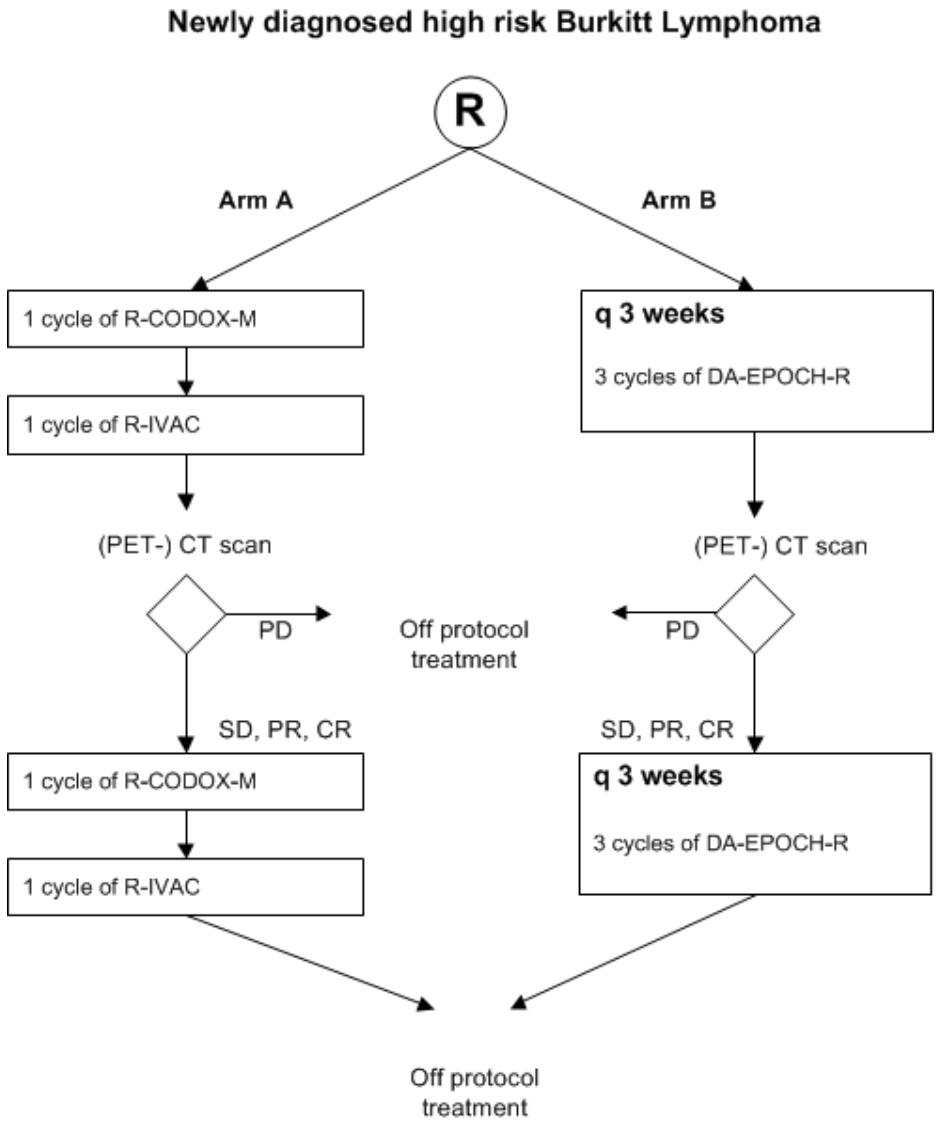
SAMENVATTING HO 127

TITEL
Randomized phase II study comparing R-CODOX-M/R-IVAC versus dose-adjusted EPOCH-R (DA-EPOCH-R) for patients with newly diagnosed high risk Burkitt lymphoma

INDICATIE
Newly diagnosed high risk Burkitt Lymphoma



Inclusion criteria

- First diagnosis of high risk Burkitt lymphoma (sporadic and HIV associated), histologically confirmed according to the WHO classification 2008;
- High risk disease; i.e. any of following: elevated LDH, WHO performance status ≥ 2 (appendix

C), Ann Arbor stage III or IV (Appendix A), tumour mass ≥ 10 cm;
- Age 18-75 years inclusive;
- WHO performance status (PS) 0-3, WHO PS 4 only if disease related (Appendix C);
- Written informed consent

Exclusion criteria

- All histopathological diagnoses other than Burkitt lymphoma according to the WHO classification 2008, irrespective of the presence of a MYC rearrangement;
- Patients with endemic Burkitt lymphoma;
- Patients with low risk Burkitt lymphoma (i.e. all of following: normal LDH, WHO performance status 0 or 1 (appendix C), Ann Arbor stage I or II (Appendix A), no tumour mass ≥ 10 cm);
- Patients with CNS localization of Burkitt lymphoma;
- Prior treatment other than local radiation (max. 10 Gy) or short course (max 7 days) of steroids ≤ 1 mg/kg for acute symptoms;
- Creatinine clearance < 50 ml/min unless lymphoma related;
- Inadequate hepatic function: bilirubin > 2.5 * ULN (total) except patients with Gilbert's syndrome as defined by > 80% unconjugated;
- Inadequate hematological function ANC < 1x10^9/l and platelets < 75x10^9 /l unless lymphoma related;
- Severe pulmonary dysfunction (CTCAE grade 3-4, see appendix D);
- Severe neurological or psychiatric disease;
- Active symptomatic ischemic heart disease, myocardial infarction, or congestive heart failure within the past year. If an ultrasound or MUGA scan is obtained the LVEF should exceed 45%;
- All men and all women of child-bearing potential not willing or able to use an acceptable method of birth control for the duration of the study and one year beyond treatment completion;
- Female subject pregnant or breast-feeding;
- History of a prior invasive malignancy in the past 5 years with the exception of basal carcinoma of the skin or stage 0 cervical carcinoma;
- Serious concomitant medical illnesses that would jeopardize the patient's ability to receive the regimen with reasonable safety, includig active hepatitis B (HBV) or hepatitis C (HCV) infection;
- Current participation in another clinical trial if interfering with HO127;
- Any psychological, familial, sociological and geographical condition potentially hampering compliance with the study protocol and follow-up schedule