An international phase II trial assessing tolerability and efficacy of sequential Methotrexate-Aracytin-based combination and R-ICE combination, followed by high-dose chemotherapy supported by autologous stem cell transplant, in patients with systemic B-cell lymphoma with central nervous system involvement at diagnosis or relapse (MARIETTA regimen)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lymphomas non-Hodgkin's B-cell
Study type	Interventional

Summary

ID

NL-OMON45024

Source
ToetsingOnline

Brief title
IELSG 42

Condition

- Lymphomas non-Hodgkin's B-cell

Synonym
B-cell lymphoma with central nervous system involvement, non hodgkin lymphoma in brain/spinal cord

Research involving
Human

Sponsors and support

Primary sponsor: IELSG Coordination Centre, Oncology Institute of Southern Switzerland
Source(s) of monetary or material Support: IELSG (central datamangement;statistics;monitoring)

Intervention

Keyword: autologous stem cell transplant, B-cell lymphoma, central nervous system involvement, Methotrexate-Aracytin

Outcome measures

Primary outcome

1-year progression-free survival (PFS)

Secondary outcome

a. Complete remission rate before autologous stem cell transplantation

b. Response duration

c. Overall survival

d. Safety

Study description

Background summary

zie paragraaf 1.2 Background van het protocol (pagina 1)

Study objective

This is an open, non comparative, multicentre phase II trial, to evaluate the efficacy and feasibility of a new
sequential combination of HD-MTX-AraC-based chemoimmunotherapy, followed by R-ICE regimen, and by
high-dose chemotherapy supported by ASCT.

Study design

Open, non comparative, multicentre phase II trial,

Intervention

All patients will be treated with Matrix (3 courses, R-ICE (3 courses), conditioning and autologous stem cell transplant.

Study burden and risks

Intensive treatment witth chemotherapy requires several hospital admissions. This is necessary to safely administer the chemotherapy, to observe the patient and to monitor side effects. this is common for most intensive treatments in hematology. Methotrexate can induce renal insufficiency and all chemotherapy can induce neutropenia and complications of infectious nature.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Histologically confirmed diagnosis of diffuse large B-cell lymphoma
- CNS involvement (brain, meninges, cranial nerves, eyes and/or spinal cord) at diagnosis (concomitant to extra-CNS disease) at diagnosis or relapse after conventional chemo(-immuno)therapy
- Diagnosis of CNS involvement either by brain biopsy or CSF cytology examination. Neuroimaging alone is acceptable when stereotactic biopsy is formally contraindicated or when the disease has been previously histologically documented in other areas and the CNS localization is concomitant with a diffuse progression of systemic disease.
- No previous treatment with high-dose methotrexate-based chemotherapy and/or brain irradiation. One-two courses of R-CHOP combination as upfront therapy are admitted in patients with large amount and/or extensive extra-CNS disease that could condition prognosis in an early phase of treatment. Local investigator decides if initial R-CHOP is needed based on patient*s conditions
- Age 18-70 years
- ECOG performance status 0-3
- written informed consent

Exclusion criteria

- Other lymphoma categories other than diffuse large B-cell lymphoma. In particular, patients with primary mediastinal lymphoma, intravascular large B-cell lymphoma or leg-type large B-cell lymphoma are excluded.
- Patients with positive flow cytometry examination of the CSF, but negative results in CSF conventional cytology, and without any other evidence of CNS disease.
- Patients with exclusive CNS disease at presentation (primary CNS lymphoma) are excluded
- Previous treatment with support of autologous or allogeneic stem cells/bone marrow transplantation.
- Symptomatic coronary artery disease, cardiac arrhythmias not well controlled with medication or
myocardial infarction within the last 6 months (New York Heart Association Class III or IV heart disease)

- Any other serious medical condition which could impair the ability of the patient to participate in the trial.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-05-2017
Enrollment:	13
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	BiCNU
Generic name:	carmustine
Product type:	Medicine
Brand name:	Cytarabine
Generic name:	Cytarabine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Mabthera
Generic name:	Rituximab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Methotrexate

Generic name:	Methotrexate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Tepadina
Generic name:	Thiotepa
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	20-06-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-12-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-05-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-07-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-08-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-08-2017

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2014-003031-19-NL
CCMO	NL54212.078.16