An explorative and feasibility study of Venetoclax combined with Tamoxifen in patients with relapsed/refractory Diffuse Large B-cell Lymphoma

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20687

Source
NTR

Brief title
TamVen

Health condition

Patients with relapsed/refractory DLBCL younger than 70 years after at least 2 lines of conventional chemotherapy. Patients with relapsed/refractory DLBCL older than 70 years after at least 1 line of conventional chemotherapy.

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: UMCG Hematology

Intervention

Outcome measures

Primary outcome

Descriptive analyses of safety and toxicity (using SAE grade 3 and 4 listing) of tamoxifen and venetoclax

Secondary outcome

• To assess the effectivity of the combination Tam and Ven as measured by the day + 28 and +90 response as measured by FDG PET CT scan.
• To assess the duration of response (DOR)
• To assess the progression free survival (PFS) after 3 months (after the first dose of TAM)
• To assess the overall survival (OS) after 3 months

Study description

Background summary

Patients with relapsed/refractory DLBCL in this study are treated with oral Venetoclax (Ven; 800 mg once daily) and oral Tamoxifen (Tam; starting with a ramp-up phase; 2 days 10mg, 2 days 20mg, and 40mg once daily). These doses are the approved doses for treatment of breast cancer (Tam) and the advised dose for the treatment of B-cell Non-Hodgkin Lymphoma (NHL). The main objectives are to asses safety and eficacy of Tam and Ven.

Study objective

TAM and ven can be used with acceptable safety and there will be a measurable overall respons. Study is exploratory, so no numbers are given yet.

Study design

at entry, prior to start Venetoclax, 24h, 72h, 7 days, 28 days and 90 days after start Venetoclax

Intervention

Patients in this study are treated with oral Ven (800 mg once daily) and oral Tam (starting with a ramp-up phase; 2 days 10mg, 2 days 20mg, and 40mg once daily). These doses are the approved doses for treatment of breast cancer (Tam) and the advised dose for the treatment of B-cell Non-Hodgkin Lymphoma (NHL)

Contacts

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Eligibility criteria

Inclusion criteria

• Patients of 18 years and older and under the age of 70 with a diagnosis of Diffuse Large B-cell lymphoma (DLBCL) and High-grade B-cell lymphoma (HGBCL) (according WHO 2016) and refractory after 2 lines of therapy. Patients with relapsed/refractory DLBCL/HGBCL older than 70 years after at least 1 line of conventional chemotherapy.
• Written informed consent.
• No known allergy to Ven or Tam.

Exclusion criteria

• Eastern Cooperative Oncology Group (ECOG) performance status >2
• Absolute neutrophil count (ANC) <1,000/µL
• Platelet count <50,000/µL
• Absolute lymphocyte count <100/µL
• Primary and secondary CNS lymphoma
• Active systemic fungal, viral or bacterial infection
• CrCl <30 mL/min calculated according to the modified formula of Cockcroft and Gault or by direct urine collection
• Pregnant or breast-feeding woman

Study design

Design

Study type: Interventional

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2021
Enrollment:	6
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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	NL9075
Other	METc UMCG : METc to be submitted

Study results