Outpatient Ifosfamide, Etoposide plus Rituximab (R-IE) for salvage in patients > 60 years with relapsed or refractory CD20 positive diffuse large B-cell lymphoma who are not candidates for stem cell transplant study

ACTRN12606000373572

Status	RECRUITING
Phase	Phase 3, Phase 4
Sponsor	Roche
Enrollment	40 participants

Plain Language Summary

This study is for older patients (60 years and above) with a type of lymphoma (blood cancer) called diffuse large B-cell lymphoma that has come back or stopped responding to treatment, and who are not well enough for an intensive stem cell transplant. The study is testing a chemotherapy combination called R-IE (Rituximab, Ifosfamide, and Etoposide) given every three weeks for six cycles, followed by two additional doses of Rituximab. A single injection of pegfilgrastim is given after each cycle to protect the immune system. The goal is to see if this outpatient treatment can control the lymphoma and improve quality of life.

You may be eligible if:
- You are 60 years of age or older
- You have CD20-positive diffuse large B-cell lymphoma that has relapsed or is not responding to first-line treatment, and you are not suitable for high-dose chemotherapy/stem cell transplant
- Your general health is good enough (ECOG performance status 0 to 2)
- Your expected survival is at least 3 months
- You are able to give written consent

You may NOT be eligible if:
- You have severe heart, liver, breathing, or kidney problems
- You are pregnant or breastfeeding
- You have a known allergy to E. coli proteins, or severe allergy to mouse-derived proteins
- You are unable to give written consent

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (1)

• Eastern Oncology Co-operative Group (ECOG) performance status 0 to 2. 2. Relapsed or progressive Cluster Designation 20 (CD20) positive diffuse large B-cell lymphoma including induction failures to first-line anthracycline-containing regimens and not usually considered eligible for high dose chemotherapy and stem cell transplantation. 3. Able to give written informed consent. 4. Life expectancy ³ 3 months

Exclusion (1)

• History of severe cardiac, hepatic, respiratory, or renal disease. 2. Poor renal function (serum creatinine > 150 µmol/L or 1.5-2.0 x Upper Limit Normal (ULN), poor hepatic function (bilirubin >30 µmol/L or >1.5x ULN; transaminases>2.5 x ULN) unless these abnormalities are related to lymphoma. 3. Poor bone marrow reserve as defined by neutrophils <1.5 x 109/L or platelets <100 x 109/L unless related to bone marrow infiltration. 4. Pregnant women or breast-feeding mothers. 5. Known hypersensitivity to E

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coli proteins, or with known anaphylaxis or IgE-mediated hypersensitivity to murine proteins, or to any component of the drugs being used. 6. Unable to provide written informed consent.

Locations (1 total)

Australia