

BMT CTN 0301

Unrelated BMT for Aplastic Anemia with Reduced Intensity Conditioning

Objective

- Determine feasibility and toxicity of fludarabine-based conditioning
- Reduce toxicity while maintaining or improving engraftment

Eligibility

- Severe Aplastic Anemia (SAA)
- 7/8 or 8/8 HLA matched unrelated donor
- Age ≤ 65 years

TREATMENT SCHEMA

Fludarabine 30 mg/m2/d on Day -5, -4, -3, -2 ATG
Thymoglobulin 3 mg/kg/d
OR
ATGAM 30 mg/kg/d

on Day -4, -3, -2

CY
Starting dose 150 mg/kg
(50 mg/kg IV daily)
on Day -4, -3, -2
(dose de-escalation depends
on engraftment and toxicity)

TBI
200 cGy at
≤ 20 cGy/minute
on Day -1

and and and

*Phase I of study tests each of four total dose levels of CY (150 mg/kg, 100 mg/kg, 50 mg/kg, 0 mg/kg) for adequate safety and graft retention.

*Phase II of study refines dose selection and allocates patients to optimal dose.

Assess for 2 years