Fludarabine 30 mg/m\(^2\)

CD19CAR CTL infusion (2x10\(^8\)/m\(^2\))

Dexamethasone 5 mg/m\(^2\)

Vincristine 1.5 mg/m\(^2\)

LCL vaccination (5x10\(^6\))

Cytoreduction

Vincristine 1.5 mg/m\(^2\)

Dexamethasone 5 mg/m\(^2\)

Lymphodepletion

Fludarabine 30 mg/m\(^2\)

Cohort 1: CD19CAR CTL alone

Cohort 2: CD19CAR CTL + Vaccination

Interim analysis

Primary Endpoints:
Toxicity (grade III/IV NCI, GVHD, hypogammaglobulinaemia)
Efficacy (BM MRD)

Secondary Endpoints:
Persistence CD19CAR CTL (flow, qPCR)
Relapse rate, DFS, OS (1, 2yrs post-SCT)

Prophylactic arm

High-risk B-ALL pre 1\(^{st}\) allo SCT

BM relapse B-ALL post allo SCT

Treat 60-70 days post 2\(^{nd}\) SCT

Pre-emptive arm

Monitor post SCT
Treat if MRD >5x10\(^{-4}\)

Treat if MRD >5x10\(^{-4}\)

Interim analysis

BM relapse B-ALL post allo SCT

High-risk B-ALL pre 1\(^{st}\) allo SCT

Treat 60-70 days post 2\(^{nd}\) SCT

Cohort 1: CD19CAR CTL alone

Cohort 2: CD19CAR CTL + Vaccination

Primary Endpoints:
Toxicity (grade III/IV NCI, GVHD, hypogammaglobulinaemia)
Efficacy (BM MRD)

Secondary Endpoints:
Persistence CD19CAR CTL (flow, qPCR)
Relapse rate, DFS, OS (1, 2yrs post-SCT)

Days

-9 -3 -2 +30 +60

LCL vaccination

LCL vaccination

LCL vaccination

Figure 1