Multivirus-specific T-cell Transfer Post SCT vs AdV, CMV and EBV Infections

NCT04832607

Status	RECRUITING
Phase	Phase 3
Sponsor	Tobias Feuchtinger
Enrollment	149 participants

Key Eligibility Criteria

Inclusion (3)

- Adult or paediatric patients (\> 2 months of age) after allogeneic stem cell transplantation (SCT) (no time restrictions apply) suffering from new or reactivated CMV or EBV or AdV infection refractory to standard antiviral treatment for two weeks (defined as no decrease or insignificant decrease of less than 1log in viral load over two weeks) as confirmed by quantitative blood PCR analysis.
- Original HSCT-donor available with an immune response at least to the virus causing the therapy-refractory (=underlying) infection.
- Written informed consent given (patient or legal representative) prior to any study-related procedures.

Exclusion (13)

- Patient with acute GvHD \> grade II or extensive chronic GvHD at the time of IMP transfer
- Patient receiving steroids (\>1 mg/kg BW Prednisone equivalent) at Screening.
- Therapeutic donor lymphocyte infusion (DLI) from 4 weeks prior to IMP infusion until 8 weeks post IMP infusion. Prescheduled prophylactic DLI d3x105 T cells/kg BW in case of T-cell depleted HSCT is not considered an exclusion criterion.
- Patient with organ dysfunction or failure as determined by Karnofsky (patients \>16 years) or Lansky (patients d16 years) score d30%
- Concomitant enrolment in another clinical trial interfering with the endpoints of this study

... and 8 more (see full listing online)

Locations (33 total)

Institut Jules Bordet (JBI), Brussels, Belgium
UZ Brussel, Brussels, Belgium
Ghent Universal Hospital (UZG), Ghent, Belgium
... and 30 more locations