

Extracellular Vesicle Treatment for Acute Respiratory Distress Syndrome (ARDS) (EXTINGUISH ARDS)

NCT05354141

Status	RECRUITING
Phase	Phase 3
Sponsor	Direct Biologics, LLC
Enrollment	970 participants

Key Eligibility Criteria

Inclusion (7)

- Men and women aged 18-75 years of age
- Presence of the following criteria for moderate to severe ARDS as defined by the Berlin Criteria within 24 hours of the first intubation:
 - Onset within 7 days of known clinical insult or requiring increasing respiratory rate, increasing oxygen flows, or increased work of breathing, and
 - Bilateral lung opacities not fully explained by pleural effusions, atelectasis, or nodules, and
 - PaO₂/FiO₂ (P/F ratio) < 200 mm Hg, and
- ... and 2 more (see full listing online)

Exclusion (14)

- Lack of signed and dated informed consent form (either by the individual or by the individual's healthcare proxy).
- Stated unwillingness to comply with all study procedures and availability for the duration of the study
- Vulnerable populations such as pregnant patients, children, individuals with severe physical or mental disabilities who cannot provide meaningful consent.
- Active malignancy requiring treatment within the last two years, with the exception of non-melanoma skin cancers.
- Major physical trauma in the last 2 days, including motor vehicle accidents, assaults, mechanical falls with sequelae of significant bleeding or craniofacial bruising, and surgeries, such that not one or more injury may be undiagnosed at time of screening.
- ... and 9 more (see full listing online)

Locations (32 total)

Direct Biologics Investigational Site, Phoenix, Arizona, United States
Direct Biologics Investigational Site, Little Rock, Arkansas, United States
Direct Biologics Investigational Site, Davis, California, United States
... and 29 more locations