Daily screening in 25 participating ICUs
N ~14,000

Patients with septic shock assessed for eligibility
n = 2060

Excluded
Failure to fulfill inclusion criteria or presence of exclusion criteria (n = 1030, 50% of shock patients)
Consent declined / not obtained (n = 514, 25% of eligible patients)

Randomised to LeoPARDS study
n = 516

Within 24 h of meeting inclusion criteria

Placebo
24h infusion
n = 258

Levosimendan
0.05-0.2 μg/kg/min for 24h
n = 258

Loss to follow-up for primary outcome measure;
withdrawal of consent after recruitment
Estimated ~3%

Analysis
n = 500
Primary outcome
Mean SOFA score in ICU

Secondary outcomes
Organ specific endpoints (cardiovascular, renal, abdominal & respiratory)
ICU free days
ICU and hospital length of stay
Duration of renal replacement therapy
Days free from catecholamine therapy
Adverse events
CCMDS data
ICU, hospital, 3 & 6 month mortality
Cardiac, renal biomarkers
Multiplex cytokine assays