Clinical Trial Details (PDF Generation Date :- Wed, 03 Aug 2016 06:27:52 GMT)

CTRI Number	Pending -
Last Modified On	
Post Graduate Thesis	No
Type of Trial	Observational
Type of Study	Investigator initiated study
Study Design	Single Arm Trial
Public Title of Study	Observational Study to evaluate the Clinical outcome with Extracorporeal Cytokine Adsorption Device (Cytosorb) in the setting of Sepsis
Scientific Title of Study	An Investigator Initiated Observational Study to evaluate the Clinical outcome with Extracorporeal Cytokine Adsorption Device (Cytosorb) in the setting of Sepsis and Septic shock patients

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Vikram Shetty
Designation	AD
Affiliation	Biocon
Address	Electronic City Bangalore Electronic City Bangalore KARNATAKA 560100 India
Phone	08067751517
Fax	
Email	vikram.shetty@biocon.com

Details Contact Person (Scientific Query)

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Name	Dr Vikram Shetty
Designation	AD
Affiliation	Biocon
Address	Electronic City Bangalore Electronic City KARNATAKA 560100 India
Phone	08067751517
Fax	
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Material support

Primary Sponsor

Primary Sponsor Details	
Name	Biocon
Address	Electronic city Bangalore
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr MANOJ SINGH	Apollo Hospital	Ahemadabad Ahmadabad GUJARAT	08067751517 drmanojsingh@rediffmail.com
Dr RAJIB PAUL	Apollo Hospital	Jubilee Hills Hyderabad ANDHRA PRADESH	08067751517 drrajibpaul@gmail.com
Dr SENTHIL KUMAR	Apollo Hospital	Chennai Chennai TAMIL NADU	08067751517 rskumaricu@gmail.com
Dr RESHMA TIWARI	ARTEMIS HOSPITAL	Gurgaon Gurgaon HARYANA	08067751517 drreshmabasu2004@yahoo.co.in
Dr SHIVAPRASAD	Narayana Hrudayalaya	Hosur road Bangalore KARNATAKA	08067751517 pradeep.y101@biocon.com
Dr PRACHEE SATHE	Ruby Hall Clinic	Sasson road Pune MAHARASHTRA	08067751517 prachee.sathe@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Apollo Hospital Ahemadabad	Submittted/Under Review	No Date Specified	No
Apollo Hospital Chennai	Submittted/Under Review	No Date Specified	No
Apollo Hospital Hyderabad	Submittted/Under Review	No Date Specified	No
ARTEMIS HOSPITAL	Submittted/Under Review	No Date Specified	No
Narayana Hrudayalaya	Submittted/Under Review	No Date Specified	No
Ruby hall clinic	Submittted/Under Review	No Date Specified	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition

Patients	sepsis and septic shock

Intervention / Comparator Agent

Type	Name	Details

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	80.00 Year(s)
Gender	Both
Details	? Male or female ? 18 and ? 80 years of age ? Patients with Suspected or confirmed diagnosis of Sepsis or Septic shock as per the Surviving sepsis guidelines hospitalized in Intensive care Unit ? Patient's must have had at least 6 hours of Sepsis bundle therapy including antibiotic therapy and other supportive therapies as per Surviving Sepsis Campaign bundle ? Evidence of at least 1 new onset organ dysfunction during this sepsis episode ? Pre-menopausal female subjects must have negative pregnancy test

Exclusion Criteria

Exclusion Criteria	
Details	? Patient is pregnant or nursing ? Established septic shock for more than 48 hrs ? More than 3 failed organs at entry ? Diagnosed with granulocytopenia (leukocyte count of less than 500 cells/mm3) and/or thrombocytopenia (platelet count of less than 20,000 cells/mm3) ? Pre-existing immune deficiencies or patient on immune –suppressive therapy ? Uncontrolled haemorrhage within the last 24 h ? Subject with active malignancy receiving chemotherapy or radiation treatment within last 60 days ? Subjects with Chronic Kidney Disease (CKD) stage 5 and with end stage hepatic liver failure will be excluded ? History of cardiopulmonary resuscitation for the current episode of sepsis ? Subject has any active disease condition including but not limited to the following: acute coronary syndrome, life-threatening cardiac arrhythmia considered by investigator(s) to preclude successful completion of the study ? Patients not willing to participate or not suitable for Cytosorb therapy as per judgment of the treating physician

Method of Generating Random Sequence

Method of Concealment	
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
? Vasopressor & Inotropic requirement to keep MAP 65 mmHg ? Percentage of patients needing reduced doses of vasopressor ? Percentage of patients needing reduced number of vasopressors drugs ? Lab parameters	seven days

Secondary Outcome

Outcome	Timepoints
Vital Parameters – HR, RR, Body temp, urine output, Blood Pressure:Mean arterial pressure [MAP] Respiratory Function – X-ray findings Ventilator requirement & Oxygenation parameters Assessment of Sepsis scores – SOFA & APACHE II scores Requirement of Renal replacement therapy, Length of ICU stay	seven days

Target Sample Size	**Total Sample Size=**0 **Sample Size from India=**50
Phase of Trial	Phase 4
Date of First Enrollment (India)	10/08/2016
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	Nil
Brief Summary	Sepsis, a syndrome of physiologic, pathologic, and biochemical abnormalities induced by infection, is a major public health concern. Sepsis-induced organ dysfunction may be occult; therefore, its presence should be considered in any patient presenting with infection. Conversely, unrecognized infection may be the cause of new-onset organ dysfunction. . Cytokines play an important role in the pathophysiology of Sepsis and other clinical conditions with Systemic Inflammatory Response Syndrome. Excess release of cytokines i.e cytokine storm during the progression of sepsis results in Multi organ Failure (MOF) causing high mortality in ICU patients. Dysregulation of the immune response during Sepsis is now recognized to be a key factor in multiple organ dysfunction, yet many therapy to address inflammation remains ineffective. It has been advocated for more than a decade that cytokine reduction in blood compartment could lead to a reduced risk of Multiorgan dysfunction and hence mortality in sepsis. Over the years, multiple extracorporeal techniques have evolved, with the intent of influencing the circulating levels of inflammatory mediators like cytokines and chemokines, the complement system, as well as factors of the coagulation system. Even with current treatment modalities the mortality rate still remains high. Cytosorb is the first-in-class therapy specifically approved as an extracorporeal cytokine filter in the European Union. Its use is broadly indicated where cytokines are elevated. Cytosorb was evaluated in European Sepsis Trial – a randomized, controlled, multi-center study in Germany in 43 patients with septic shock and respiratory failure (predominantly ARDS).Cytosorb plus standard of care (SOC) therapy achieved the primary endpoint of demonstrating the statistically significant reduction from baseline of many key cytokines by 30-50%. These findings are consistent with ex vivo serum perfusion experiments where Cytosorb also reduced a broad spectrum of cytokines in this ~10-55 kDa range Through this real time Investigator initiated Observational study we would like to evaluate the clinical outcome with Cytosorb device treatment along with current standard of care in management of Sepsis and Septic shock.