# The Effects of Polymyxin-B Protects on Sepsis Induced Kidney Dysfunction: a Randomized Clinical Trial

**This study has been completed.**

First Received: June 20, 2007 Last Updated: June 4, 2010 History of Changes

| | |
|---|---|
| **Sponsor:** | University of Turin, Italy |
| **Information provided by:** | University of Turin, Italy |
| **ClinicalTrials.gov Identifier:** | NCT00490477 |

## Purpose

Aim of the study is to verify whether Polymyxin-B hemoperfusion protects from renal dysfunction in patients with severe sepsis from gram negative infection.

| Condition | Intervention | Phase |
|---|---|---|
| Gram-Negative Bacterial Infections<br>Sepsis | Device: **Polymyxin -B** fiber hemoperfusion system | Phase III |

Study Type: Interventional
Study Design: Allocation: Randomized
Control: Active Control
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Prevention

Official Title: **Polymyxin-B** Hemoperfusion Inactivates Circulating Proapoptotic Factors

**Resource links provided by NLM:**

MedlinePlus related topics: Bacterial Infections Dietary Fiber Sepsis

Drug Information available for: Polymyxin B Polymyxin B Sulfate

U.S. FDA Resources

**Further study details as provided by University of Turin, Italy:**

Primary Outcome Measures:

- Number of Participants Not Requiring Renal Replacement Therapy (RRT) [ Time Frame: 28 days from the admission ] [ Designated as safety issue: No ]

Secondary Outcome Measures:

- The Reduction of the Number of Apoptotic Cells, Stimulated With Plasma Derives From Septic Patients With Gram Negative Infection, Treated With PMX-B Hemoperfusion, on Immortalized Tubular and Glomerular Cell Cultures. [ Time Frame: 72 hours after randomization ] [ Designated as safety issue: No ]

Enrollment: 16
Study Start Date: May 2006
Study Completion Date: December 2007
Primary Completion Date: July 2007 (Final data collection date for primary outcome measure)

| Arms | Assigned Interventions |
|---|---|
| CONVENTIONAL: No Intervention | |
| **POLYMYXIN-B**: Active Comparator<br>an extracorporeal LPS removal<br>Intervention: Device: **Polymyxin -B** fiber hemoperfusion system | Device: **Polymyxin -B** fiber hemoperfusion system<br>two hours treatment for two days<br>Other Name: PMX-B |

**Detailed Description:**
Acute renal failure (ARF) is a frequent complication in sepsis, in nearly to 50% of the cases, and the mortality rate is higher, compare to patients with ARF alone (70% vs 45%). Clinical and experimental studies demonstrated the key role of apoptosis, or programmed cell death, in the induction of tubular and glomerular injury in the course of sepsis. Indeed, it has been shown that inflammatory cytokines and lipopolysaccharide (LPS) cause renal tubular cell apoptosis via Fas- and caspase-mediated pathways. In addition, LPS is able to alter the normal expression pattern of sodium, urea and glucose renal transporters and to modulate tubular polarity by changing the expression of tight junction proteins with consequent back-leakage of tubular fluid in the interstitial spaces and enhancement of the inflammatory process. Therefore a novel extracorporeal therapy to remove circulating LPS, using the Polymyxin-B fiber (PMX-B) cartridge was developed. The PMX-B cartridge is an extracorporeal hemoperfusion device and consists of a polystyrene-based, fibrous adsorbent on which the polymyxin B antibiotic is covalently immobilized as a ligand to adsorb endotoxin.

Aim of this study is to verify whether the removal of LPS, using the PMX-B hemoperfusion system, protects from acute renal failure, reduces the need for Renal Replacement Therapy (RRT) and consequently improves the outcome in severe sepsis from gram negative infection.

## Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

**Criteria**

Inclusion Criteria:

- Endotoxemia associated to severe sepsis

Exclusion Criteria:

- Age < 18 years old
- Organ transplantation
- Hemorrhagic shock
- Thrombophilia
- Chronic renal failure
- Cardiogenic shock
- APACHE II score > 30
- Lack of consent

## Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00490477

**Locations**

**Italy**

University of Turin, Department of anesthesia and Intensive Care Medicine
Turin, Italy, 10126

**Sponsors and Collaborators**

University of Turin, Italy

**Investigators**

Study Director: marco ranieri, MD University of Turin, Department of Anesthesia and Intensive Care Medicine
Principal Investigator: marco ranieri, MD University of Turin, Department of Anesthesia and Intensive Care Medicine

## More Information

Publications:

Cantaluppi V, Assenzio B, Pasero D, Romanazzi GM, Pacitti A, Lanfranco G, Puntorieri V, Martin EL, Mascia L, Monti G, Casella G, Segoloni GP, Camussi G, Ranieri VM. Polymyxin-B hemoperfusion inactivates circulating proapoptotic factors. Intensive Care Med. 2008 Sep;34(9):1638-45. Epub 2008 May 8.

| | |
|---|---|
| Responsible Party: | University of Turin ( V. M. Ranieri, MD ) |
| ClinicalTrials.gov Identifier: | NCT00490477 History of Changes |
| Other Study ID Numbers: | N-257 |
| Study First Received: | June 20, 2007 |
| Results First Received: | March 9, 2010 |
| Last Updated: | June 4, 2010 |
| Health Authority: | Italy: Ministry of Health |

Keywords provided by University of Turin, Italy:

acute renal failure
lipopolysaccharide
tubular apoptosis
**Polymyxin-B** fiber
Severe sepsis from gram negative infection

Additional relevant MeSH terms:

| | |
|---|---|
| **Polymyxin B** | Pathologic Processes |
| Bacterial Infections | Polymyxins |
| Sepsis | Anti-Bacterial Agents |
| Gram-Negative Bacterial Infections | Anti-Infective Agents |
| Infection | Therapeutic Uses |
| Systemic Inflammatory Response Syndrome | Pharmacologic Actions |
| Inflammation | |

ClinicalTrials.gov processed this record on November 15, 2010



# Early Use of Polymyxin B Hemoperfusion in Abdominal Sepsis (EUPHAS)

**This study has been completed.**

First Received: February 26, 2008 Last Updated: December 1, 2008 History of Changes

| | |
|---|---|
| **Sponsor:** | St. Bortolo Hospital |
| **Information provided by:** | St. Bortolo Hospital |
| **ClinicalTrials.gov Identifier:** | NCT00629382 |

## Purpose

This clinical study designed as a prospective, open labelled, multi-centre, RCT will be carried out to evaluate if direct hemoperfusion with polymyxin B immobilized fiber column (PMX) is superior to conventional medical therapy for sepsis, for patients with sepsis arising from abdominal cavity infection, accompanied by the failure of one or more organs. 120 patients (60 treatment/60 control) will be considered in this study. Those patients fulfilling inclusion criteria and not having exclusion criteria will be randomly allocated to one of two study groups. One group will be treated with PMX (PMX group) and the other will receive a "standard therapy" for sepsis (control group). All patients will receive full intensive care management, including fluid resuscitation, vasopressors, antimicrobial chemotherapy, ventilatory support, and renal replacement therapy, if required. Each patient will be followed up for 28 days after study entry.

| Condition | Intervention | Phase |
|---|---|---|
| Gram-Negative Bacterial Infections<br>Sepsis<br>Septic Shock | Device: **Polymyxin B** immobilized fiber column<br>Other: Conventional medical therapy in the ICU | Phase IV |

Study Type: Interventional
Study Design: Allocation: Randomized
Control: Active Control
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Dispositivo Adsorbente Con Polymyxina B Immobilizzata Nello Shock Settico - Studio Clinico Randomizzato e Prospettico, Multicentrico

**Resource links provided by NLM:**

MedlinePlus related topics: Bacterial Infections Dietary Fiber Sepsis

Drug Information available for: Polymyxin B Polymyxin B Sulfate

U.S. FDA Resources

**Further study details as provided by St. Bortolo Hospital:**

Primary Outcome Measures:

- Blood pressure and use of vasopressors [ Time Frame: 48-72 hrs ] [ Designated as safety issue: No ]

Secondary Outcome Measures:

- PaO2/ FiO2 ratio [ Time Frame: 48-72 hrs ] [ Designated as safety issue: No ]
- Change in SOFA score [ Time Frame: 48-72 hrs ] [ Designated as safety issue: No ]
- ICU survival [ Time Frame: 28 days ] [ Designated as safety issue: No ]

Enrollment: 70
Study Start Date: December 2004
Study Completion Date: April 2008
Primary Completion Date: April 2008 (Final data collection date for primary outcome measure)

| Arms | Assigned Interventions |
|---|---|
| 1: Experimental<br>Interventions:<br>• Device: **Polymyxin B** immobilized fiber column<br>• Other: Conventional medical therapy in the ICU | Device: **Polymyxin B** immobilized fiber column<br>Hemoperfusion with PMX will be performed in ICU. The 1st PMX treatment (day 0) will be carried out for 2 hours and ideally within 24 hours but not later than 48 hours after diagnosis of severe sepsis. The second PMX treatment has to be performed 24 to 48 hours after the end of the first PMX treatment, ideally after 24 hours. Hemoperfusion therapy will be performed in addition to conventional medical therapy in the ICU.<br>Other Name: Toraymyxin<br>Other: Conventional medical therapy in the ICU<br>Including, but not limited to: antibiotic therapy, nutrition, administration of gamma-globulins, vasopressors, hemodynamic monitoring, organ support in the ICU including mechanical ventilation, corrective measures for metabolic abnormalities, renal replacement therapy when appropriate. |
| 2<br>Intervention: Other: Conventional medical therapy in the ICU | Other: Conventional medical therapy in the ICU<br>Including, but not limited to: antibiotic therapy, nutrition, administration of gamma-globulins, vasopressors, hemodynamic monitoring, organ support in the ICU including mechanical ventilation, corrective measures for metabolic abnormalities, renal replacement therapy when appropriate. |

## Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

**Criteria**

Inclusion Criteria:

- Patients with severe sepsis due to intra-abdominal cavity infection after emergency surgery with at least 2 SIRS criteria and 1 organ dysfunction (as defined by SCCM)

Exclusion Criteria:

- Less than 18 years of age
- Females with a positive pregnancy test
- Treated with another investigational drug or device within the 30 days immediately preceding enrolment in this study
- Undergone organ transplantation during the past one year
- Documented history of sensitivity to Polymyxin-B, anticoagulant (heparin)
- Terminally ill, including metastases or hematological malignancy, with a life expectancy less than 30 days (as assessed by the attending physician) or have been classified as "Do Not Resuscitate"
- Diagnosed with HIV
- Previous history of end stage chronic organ failure(s)

- Uncontrolled hemorrhage within the last 24 h
- Diagnosed with granulocytopenia (leukocyte count of less than 500 cells/mm3) and/or thrombocytopenia (platelet count of less than 30,000 cells/mm3)
- More than 4 failed organs at entry
- An APACHE II score of more than 30 at entry to the study

## Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00629382

### Locations

**Italy**

St Bortolo Hospital
Vicenza, Italy, 36100

### Sponsors and Collaborators

St. Bortolo Hospital

## More Information

Publications:

Cruz DN, Perazella MA, Bellomo R, de Cal M, Polanco N, Corradi V, Lentini P, Nalesso F, Ueno T, Ranieri VM, Ronco C. Effectiveness of polymyxin B-immobilized fiber column in sepsis: a systematic review. Crit Care. 2007;11(2):R47. Review.

Additional publications automatically indexed to this study by National Clinical Trials Identifier (NCT ID):

Cruz DN, Antonelli M, Fumagalli R, Foltran F, Brienza N, Donati A, Malcangi V, Petrini F, Volta G, Bobbio Pallavicini FM, Rottoli F, Giunta F, Ronco C. Early use of polymyxin B hemoperfusion in abdominal septic shock: the EUPHAS randomized controlled trial. JAMA. 2009 Jun 17;301(23):2445-52.

| | |
|---|---|
| Responsible Party: | International Renal Research Institute Vicenza (IRRIV), ( Claudio Ronco, MD ) |
| ClinicalTrials.gov Identifier: | NCT00629382 History of Changes |
| Other Study ID Numbers: | TM05 |
| Study First Received: | February 26, 2008 |
| Last Updated: | December 1, 2008 |
| Health Authority: | Italy: Ministry of Health |

Keywords provided by St. Bortolo Hospital:

| | |
|---|---|
| abdominal sepsis | **polymyxin B** |
| abdominal surgery | hemoperfusion |
| septic shock | Endotoxins |

Additional relevant MeSH terms:

| | |
|---|---|
| **Polymyxin B** | Inflammation |
| Bacterial Infections | Pathologic Processes |
| Sepsis | Polymyxins |
| Shock | Anti-Bacterial Agents |
| Shock, Septic | Anti-Infective Agents |
| Gram-Negative Bacterial Infections | Therapeutic Uses |
| Infection | Pharmacologic Actions |
| Systemic Inflammatory Response Syndrome | |

ClinicalTrials.gov processed this record on November 15, 2010



# Safety and Efficacy of Polymyxin B Hemoperfusion (PMX) for Septic Shock (EUPHRATES)

**This study is currently recruiting participants.**
Verified by Spectral Diagnostics (US) Inc., July 2010

First Received: January 8, 2010 Last Updated: October 6, 2010 History of Changes

| | |
|---|---|
| **Sponsor:** | Spectral Diagnostics (US) Inc. |
| **Collaborator:** | Clinquest, Inc. |
| **Information provided by:** | Spectral Diagnostics (US) Inc. |
| **ClinicalTrials.gov Identifier:** | NCT01046669 |

## Purpose

To compare the safety and efficacy of the PMX cartridge based on mortality at 28-days in subjects with septic shock who have high levels of endotoxin and are treated with standard medical care plus use of the PMX cartridge, versus subjects who receive standard medical care alone.

| Condition | Intervention | Phase |
|---|---|---|
| Septic Shock<br>Endotoxemia | Device: TORAYMYXIN PMX-20R (PMX cartridge) | Phase III |

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Evaluating the Use of Polymyxin B Hemoperfusion in a Randomized Controlled Trial of Adults Treated for Endotoxemia and Septic Shock

**Resource links provided by NLM:**

Drug Information available for: Polymyxin B Polymyxin B Sulfate

U.S. FDA Resources

**Further study details as provided by Spectral Diagnostics (US) Inc.:**

Primary Outcome Measures:

- Mortality [ Time Frame: 28 days ] [ Designated as safety issue: No ]

Secondary Outcome Measures:

- To compare mortality between the two groups at 90 days, 6 months and 12 months post-start of treatment [ Time Frame: 12 months ] [ Designated as safety issue: No ]

Estimated Enrollment: 360

| | |
|---|---|
| Study Start Date: | June 2010 |
| Estimated Study Completion Date: | January 2014 |
| Estimated Primary Completion Date: | January 2013 (Final data collection date for primary outcome measure) |

| Arms | Assigned Interventions |
|---|---|
| Control: Sham Comparator<br>Intervention: Device: TORAYMYXIN PMX-20R (PMX cartridge) | Device: TORAYMYXIN PMX-20R (PMX cartridge)<br>Extracorporeal hemoperfusion device Each treatment will target 2 hours with a minimum of 1 ½ hours, at a flow rate of approximately 100 ml/minute, (range of 80 to 120 ml/minute). |
| Treatment: Experimental<br>Two (2) PMX cartridges will be administered approximately 24 hours apart.<br>Intervention: Device: TORAYMYXIN PMX-20R (PMX cartridge) | Device: TORAYMYXIN PMX-20R (PMX cartridge)<br>Extracorporeal hemoperfusion device Each treatment will target 2 hours with a minimum of 1 ½ hours, at a flow rate of approximately 100 ml/minute, (range of 80 to 120 ml/minute). |

## Eligibility

| | |
|---|---|
| Ages Eligible for Study: | 18 Years and older |
| Genders Eligible for Study: | Both |
| Accepts Healthy Volunteers: | No |

**Criteria**

Inclusion Criteria:

- Hypotension requiring vasopressor support
- The subject must have received intravenous fluid resuscitation
- Documented or suspected infection
- Endotoxin Activity Assay ≥ 0.60 EAA units
- Evidence of at least 1 new onset organ dysfunction

Exclusion Criteria:

- Inability to achieve or maintain a minimum mean arterial pressure (MAP) of 65mmHg
- Subject has end stage renal disease and requires chronic dialysis
- There is clinical support for non-septic shock
- Subject has had chest compressions as part of CPR
- Subject has had an acute myocardial infarction (AMI)
- Subject has uncontrolled hemorrhage
- Major trauma within 36 hours of screening
- Subject has severe granulocytopenia
- HIV infection with a last known or suspected CD4 count of <50/mm3
- Subject has sustained extensive third-degree burns
- Body weight < 35 kg (77 pounds)
- Known hypersensitivity to polymyxin B
- Subject has known sensitivity or allergy to heparin

## Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01046669

**Locations**

**United States, New Jersey**

Cooper University Hospital **Recruiting**
Camden, New Jersey, United States, 08103
Contact: Phillip Dellinger, MD 856-342-2632 Dellinger-Phil@CooperHealth.edu

**United States, Pennsylvania**

Temple University Hospital **Not yet recruiting**
Philadelphia, Pennsylvania, United States, 19140
Contact: Gerard Criner, Dr. 215-707-8113 Gerard.criner@tuhs.temple.edu

**United States, Rhode Island**

Rhode Island Hospital **Recruiting**
Providence, Rhode Island, United States, 02903
Contact: Mitchell M Levy, MD 401-444-8410 mitchell_Levy@brown.edu

**Sponsors and Collaborators**

Spectral Diagnostics (US) Inc.

Clinquest, Inc.

**Investigators**

Principal Investigator: Phillip Dellinger, MD The Cooper Health System

## More Information

No publications provided

| | |
|---|---|
| Responsible Party: | Spectral Diagnostics (US) Inc. ( Debra Foster ) |
| ClinicalTrials.gov Identifier: | NCT01046669 History of Changes |
| Other Study ID Numbers: | SDI-PMX-NA001 |
| Study First Received: | January 8, 2010 |
| Last Updated: | October 6, 2010 |
| Health Authority: | United States: Food and Drug Administration |

Additional relevant MeSH terms:

| | |
|---|---|
| Shock | Bacteremia |
| Shock, Septic | Toxemia |
| Endotoxemia | Polymyxin B |
| Pathologic Processes | Polymyxins |
| Sepsis | Anti-Bacterial Agents |
| Infection | Anti-Infective Agents |
| Systemic Inflammatory Response Syndrome | Therapeutic Uses |
| Inflammation | Pharmacologic Actions |

ClinicalTrials.gov processed this record on November 15, 2010



# Effects of Hemoperfusion With a Polymixin B Membrane in Peritonitis With Septic Shock (ABDO-MIX)

**This study is currently recruiting participants.**
Verified by Meditor SAS, November 2010

First Received: October 8, 2010 Last Updated: November 15, 2010 History of Changes

| | |
|---|---|
| **Sponsor:** | Meditor SAS |
| **Information provided by:** | Meditor SAS |
| **ClinicalTrials.gov Identifier:** | NCT01222663 |

## Purpose

The purpose of this randomized, comparative, open and multi-centre study is to show that two sessions of hemoperfusion with Toraymixin performed within maximum 36 hours after the surgery of a peritonisis by hollow organ perforation reduce the mortality in patients suffering from septic shock.

| Condition | Intervention | Phase |
|---|---|---|
| Peritonitis<br>Septic Shock | Device: standard therapy<br>Device: hemoperfusion | Phase III |

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Effects of Hemoperfusion With a Polymixin B Membrane in Peritonitis With Septic Shock

**Resource links provided by NLM:**

Drug Information available for: Polymyxin B Polymyxin B Sulfate

U.S. FDA Resources

**Further study details as provided by Meditor SAS:**

Primary Outcome Measures:

- Mortality [ Time Frame: 28 days ] [ Designated as safety issue: Yes ]

Secondary Outcome Measures:

- organ failure assessed by SOFA score [ Time Frame: day 3 ]
  [ Designated as safety issue: Yes ]
- delay to withdraw catecholamine after initial shock [ Time Frame: day 1-day 28 ]
  [ Designated as safety issue: No ]
- mortality between the two groups at 7 dayx, 14 days, 21 days and 90 days [ Time Frame: 90 days ] [ Designated as safety issue: No ]
- number of participants with adverse events related to hemoperfusion technique including anticoagulation therapy such as bleeding (type and number of blood transfusion)
  [ Time Frame: day1-day4 ] [ Designated as safety issue: Yes ]

| | |
|---|---|
| Estimated Enrollment: | 240 |
| Study Start Date: | October 2010 |
| Estimated Study Completion Date: | June 2012 |
| Estimated Primary Completion Date: | April 2012 (Final data collection date for primary outcome measure) |

| Arms | Assigned Interventions |
|---|---|
| Standard therapy: No Intervention<br>include but not limited to: iv fluids, catecholamine infusion, antibiotics, extrarenal therapy if necessary, mechanical ventilation<br>Intervention: Device: standard therapy | Device: standard therapy<br>Standard therapy in the ICU including but not limited to: antibiotic therapy, nutrition, fluid challenge, vasopressors, hemodynamic monitoring, organ support in the ICU including mechanical ventilation, renal replacement therapy when appropriate<br>Other Name: Toraymyxin |
| Hemoperfusion: Experimental<br>standard therapy + 2 sessions of hemoperfusion within the first 24 hours<br>Interventions:<br>• Device: standard therapy<br>• Device: hemoperfusion | Device: standard therapy<br>Standard therapy in the ICU including but not limited to: antibiotic therapy, nutrition, fluid challenge, vasopressors, hemodynamic monitoring, organ support in the ICU including mechanical ventilation, renal replacement therapy when appropriate<br>Other Name: Toraymyxin<br>Device: hemoperfusion<br>Extracorporeal hemoperfusion with Toraymyxin PMX-20R and conventional medical therapy in the ICU including but not limited to: antibiotic therapy, nutrition, fluid challenge, vasopressors, hemodynamic monitoring, organ support in the ICU including mechanical ventilation, renal replacement therapy when appropriate.<br>Other Name: toraymyxin |

**Detailed Description:**

The mortality rate due to peritonitises associated to a severe sepsis or a septic shock remains high (between 40 and 60% as per the studies). The recent complementary therapies for severe sepsis have been reassessed (strict glycaemic control, substitutive corticotherapy, activated protein C). Early neutralisation of the endotoxinemia related to gram-negative bacilli sepsis in contact with hemoperfusion membrane covered with polymyxin B (Toraymyxine™) may enable reduction of the inflammatory reaction caused by sepsis and improve its prognosis. 30 studies, including 10 randomized studies, have compared hemoperfusion with Toraymyxine™ to the standard treatment, showing an improvement in the patients' haemodynamic state, oxygenation conditions and reduction in mortality. This treatment is commonly used in Japan. However, the studies conducted either include only a limited number of patients or are not randomized prospective studies. The post-hoc analysis of a recent randomized study conducted on a limited number of patients with abdominal septic shock shows a significant reduction in mortality after factor adjustment. Though the side effects of such a treatment are limited, its cost is high. Hence, extensive prospective studies are necessary to confirm its effectiveness.

## Eligibility

| | |
|---|---|
| Ages Eligible for Study: | 18 Years and older |
| Genders Eligible for Study: | Both |
| Accepts Healthy Volunteers: | No |

**Criteria**

Inclusion Criteria:

- Confirmed community or nosocomial acquired peritonitis due to organ perforation
- Septic shock requiring catecholamine infusion started or maintained 2 hours after surgery

Exclusion Criteria:

- Pregnancy
- No severity criterai within the 8 hours following surgery

- Neutropenia due to chempotherapy or malignancy
- Abdominal sepsis without peritonitis
- Mesentric ischemia without perforation
- Peritonitis due to appendicitis
- Perforation linked to trauma
- Cirrhosis child C
- Impossibility to use heparin
- Prolonged cardiac arrest within 72h before surgery
- Terminal disease diagnosed during surgery
- Moribund subjects

## Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01222663

### Locations

#### France

Clermont-Ferrand University Hospital **Not yet recruiting**
Clermont-Ferrand, France, 63058
Contact: Jean-Michel Constantin, physician 0033473750501 jmconstantin@chu-clermontferand.fr
Principal Investigator: Jean-Michel Constantin, physician
Sub-Investigator: Matthieu Jabaudon, physician
Sub-Investigator: Sophie Cayot-Constantin, physician
Sub-Investigator: Renaud Guerin, physician
Sub-Investigator: Christian Chartier, physician
Sub-Investigator: Sébastien Perbet, physician

Dieppe Hospital **Not yet recruiting**
Dieppe, France, 76202
Contact: Nicolas Devos, physician 0033232147118 ndevos@ch-dieppe.fr
Principal Investigator: Nicolas Devos, physician
Sub-Investigator: Jean-Philippe Rigaud, physician
Sub-Investigator: Jean-Pierre Eraldi, physician
Sub-Investigator: François Bougerol, physician
Sub-Investigator: Jean-Charles Chakarian, physician
Sub-Investigator: Igor Auriant, physician

Vendée Hospital **Not yet recruiting**
La Roche sur Yon, France, 85925
Contact: Laurent Martin-Lefèvre, physician 0033251446088 laurent.martin-lefevre@chd-vendee.fr
Principal Investigator: Laurent Martin-Lefevre, physician
Sub-Investigator: Jean Reigner, physician
Sub-Investigator: Eva Clementi, physician
Sub-Investigator: Maud Fiancette, physician
Sub-Investigator: Isabelle Vinatier, physician

Dr Schaffner Hospital **Not yet recruiting**
Lens, France, 62307
Contact: Didier Thevenin, physician 0033321691088 dthevenin@ch-lens.fr
Principal Investigator: Jihad Mallat, physician
Sub-Investigator: Didier Thevenin, physician
Sub-Investigator: Laurent Tronchon, physician
Sub-Investigator: Malcolm Lemyre, physician
Sub-Investigator: Gaëlle Gasan, physician
Sub-Investigator: Florent Pepy, physician
Sub-Investigator: Christine Pruvot, physician

Lille University Hospital **Not yet recruiting**
Lille, France, 59037
Contact: Bernard Leroy, Physician 0033320444401 bernard.leroy@chru-lille.fr
Principal Investigator: Bernard Leroy, Physician
Sub-Investigator: Eric Kipnis, Physician
Sub-Investigator: Pierre-André Rodie-Talbere, Physician

Limoges University Hospital **Not yet recruiting**
Limoges, France, 87042
Contact: Anthony Dugard, Physician 0033555056254 anthony.dugard@chu-limoges.fr
Principal Investigator: Anthony Dugard, Physician
Sub-Investigator: Philippe Vignon, MD

Sub-Investigator: Jean-Bernard Amiel, Physician
Sub-Investigator: Bruno François, Physician
Sub-Investigator: Gwenaelle Lheritier, Physician
Sub-Investigator: Marc Clavel, Physician
Sub-Investigator: Nicolas Pichon, Physician
Sub-Investigator: Déborah Postil, Physician

Annecy Hospital **Not yet recruiting**
Metz-Tessy, France, 74374
Contact: Didier Dorez, physician 0033450636305 ddorez@ch-annecy.fr
Principal Investigator: Didier Dorez, physician
Sub-Investigator: Michel Sirodot, physician
Sub-Investigator: Renaud Chouquer, physician

Nice University Hospital **Not yet recruiting**
Nice, France, 06000
Contact: Carole Ichai, MD 0033492033558 ichai@unice.fr
Principal Investigator: Carole Ichai, MD
Sub-Investigator: Jean-Christophe Orban, Physician
Sub-Investigator: Hervé Quintard, Physician
Sub-Investigator: Corine Samat-Long, Physician

La Source Hospital **Not yet recruiting**
Orleans, France, 45067
Contact: Thierry Boulain, Physician 0033238514446 thierry.boulain@chr-orleans.fr
Principal Investigator: Thierry Boulain, Physician
Sub-Investigator: Armelle Sylvie Mathonnet, Physician
Sub-Investigator: Dalila Benzekri Lefevre, Physician
Sub-Investigator: Anne Bretagnol, Physician

Lariboisière University Hospital **Not yet recruiting**
Paris, France, 75010
Contact: Didier Payen, MD 0033149958085 dpayen1234@orange.fr
Principal Investigator: Didier Payen, MD
Sub-Investigator: Joaquim Mateo, physician
Sub-Investigator: Anne-Claire Lukaszewicz, physician
Sub-Investigator: Thomas Poussant, physician

Saint Louis Hospital **Not yet recruiting**
Paris, France, 75475
Contact: Laurent Jacob, MD 0033142494830 laurent.jacob@sls.aphp.fr
Principal Investigator: Laurent Jacob, MD
Sub-Investigator: Chloé Le Gall, Physician

François Mitterand Hospital **Not yet recruiting**
Pau, France, 64046
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Principal Investigator: Jean-Noël Drault, Physician
Sub-Investigator: Philippe Badia, Physician
Sub-Investigator: Paul Aye, Physician
Sub-Investigator: Paul Bonneil, Physician
Sub-Investigator: Walter Picard, Physician
Sub-Investigator: Anne-Claire Volatron, Physician
Sub-Investigator: Franck Decamps, Physician

Bordeaux University Hospital **Recruiting**
Pessac, France, 33600
Contact: Olivier Joannes-Boyau, MD 0033557656866 olivier.joannes-boyau@chu-bordeaux.fr
Principal Investigator: Olivier Joannes-Boyau, MD
Sub-Investigator: Antoine Dewitte, physician
Sub-Investigator: Catherine Fleureau, physician
Sub-Investigator: Stéphane Rapaport, physician
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Sub-Investigator: Franck Petitpas, physician
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Sub-Investigator: Edgar Menguy, Physician
Sub-Investigator: Caroline Abriou Guerin, Physician
Sub-Investigator: Dorothée Carpentier, Physician
Sub-Investigator: Nathalie Rey, Physician

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Sub-Investigator: Vlad Botoc, Physician
Sub-Investigator: Nathalie Guinard, Physician
Sub-Investigator: Daniel Hermes, Physician
Sub-Investigator: Philippe Detouche, Physician
Sub-Investigator: Stéphanie Chevalier, Physician
Sub-Investigator: Mathieu Dupont, Physician

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Sub-Investigator: Olivier Martinet, Physician
Sub-Investigator: Hassene Rahmani, Physician
Sub-Investigator: Christine Kummerlen, Physician
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Tours University Hospital **Not yet recruiting**
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### Sponsors and Collaborators

Meditor SAS

### Investigators

Principal Investigator: Didier Payen, MD Lariboisière University Hospital

Principal Investigator: René Robert, MD Poitiers University Hospital

## More Information

No publications provided

| | |
|---|---|
| Responsible Party: | Meditor SAS ( Luc Perrault / Development in-charge ) |
| ClinicalTrials.gov Identifier: | NCT01222663 History of Changes |
| Other Study ID Numbers: | 2010-67-PMX |
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peritonitis

septic shock
hemoperfusion
polymyxinB
endotoxin

Additional relevant MeSH terms:

| | |
|---|---|
| Peritonitis | Systemic Inflammatory Response Syndrome |
| Shock | Inflammation |
| Shock, Septic | Polymyxin B |
| Peritoneal Diseases | Polymyxins |
| Digestive System Diseases | Anti-Bacterial Agents |
| Pathologic Processes | Anti-Infective Agents |
| Sepsis | Therapeutic Uses |
| Infection | Pharmacologic Actions |

ClinicalTrials.gov processed this record on November 15, 2010