

**International Randomized Trial to Evaluate The Effectiveness of The Portable Organ Care System
(OCS™) Liver For Preserving and Assessing Donor Livers for Transplantation
(OCS Liver PROTECT Trial)**



Protocol Number OCS-LVR-072014

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OCS™ Liver PROTECT Trial Synopsis

Protocol Title	International Randomized Trial to Evaluate The Effectiveness of The Portable Organ Care System (OCS™) Liver For Preserving and Assessing Donor Livers for Transplantation (OCS™ Liver PROTECT Trial)
Objectives	To evaluate the effectiveness of the OCS™ Liver to preserve and assess donor livers intended for transplantation
Trial Design	A prospective, pivotal, international randomized trial
Trial Size	A maximum of 20 participating sites worldwide with 300 transplanted liver recipients
Screening and Treatment	<p>Donor livers will be screened for trial eligibility. Eligible donor livers will be preserved either using the OCS™ Liver system (OCS group) or cold flush and storage using cold preservation solution (SOC group)</p> <p>Primary Liver transplant candidates will be screened for trial eligibility. Every eligible candidate will be asked to participate. Eligible liver transplant candidates will be randomized to receive either a donor liver preserved either on OCS™ Liver (OCS) or using cold preservation solution (SOC)</p>
Donor Liver Eligibility Criteria	<p>Inclusion</p> <p>Donor livers suitable for preservation with either OCS or SOC and meets at least one of the following:</p> <ul style="list-style-type: none"> • Donor age ≥40 years old • Expected cross clamp time ≥4 hours • Donor after circulatory death (DCD) with age ≤ 55 years old • Steatotic liver ≤ 40% macrosteatosis at time of retrieval (based on clinical diagnosis or histology at time of liver retrieval) <p>Exclusion</p> <ul style="list-style-type: none"> • Liver in which investigator is unwilling to randomize to either arm • Living donors • Liver intended for split transplants • Positive serology (HIV, Hepatitis B & C) • Presence of moderate or severe traumatic liver injury
Recipient Eligibility Criteria	<p>Inclusion</p> <ul style="list-style-type: none"> • Registered male or female primary Liver transplant candidate • Age ≥18 years old • Signed: 1) written informed consent document and 2) authorization to use and disclose protected health information

	Exclusion <ul style="list-style-type: none"> • Acute, fulminant liver failure • Prior solid organ or bone marrow transplant • Chronic use of hemodialysis or diagnosis of chronic renal failure, defined as chronic serum creatinine of >3 mg/dl for >2 weeks and/or requiring hemodialysis • Multi-organ transplant
Primary Endpoint	<p>Primary liver graft dysfunction defined as presentation of one or more of the following criteria:</p> <ul style="list-style-type: none"> • AST level > 2000 IU/ml within the first 7 postoperative days; • Bilirubin \geq 10 mg/dl on postoperative day 7; • INR \geq 1.6 on postoperative day 7; or • Primary non-functioning graft
Secondary Endpoints	<ul style="list-style-type: none"> • Patient survival at day-30 post transplantation • Graft survival at day-30 post transplant • Need for Renal replacement therapy, defined as requiring >2 dialysis treatments in the first 10 days post liver transplantation
Other Endpoints	<ul style="list-style-type: none"> • Length of initial post-transplant ICU stay • Length of initial post-transplant hospital stay • Evidence of biliary strictures diagnosed at 6, 12 or 24 months
Safety Endpoints	<p>Incidence of liver graft related Serious Adverse Events (SAEs) in the first 30 days post liver transplantation, defined as:</p> <ul style="list-style-type: none"> • Primary non-function (defined as irreversible graft dysfunction requiring emergency liver re-transplantation or death with the first 10 days, in the absence of immunologic or technical causes); • Biopsy proven acute rejection; • Biliary complications (biliary strictures, anastomotic and non-anastomotic bile duct leaks); • Vascular complications (non-surgical bleeding, hepatic artery stenosis, hepatic artery thrombosis and portal vein thrombosis); • Liver graft related infections (liver abscess, cholangitis, etc.)
Follow-up	All patients will be followed for up to 2 years post-transplant.
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