

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Trial record 1 of 1 for: nct01148199

[Previous Study](#) | [Return to List](#) | [Next Study](#)**Self-expandable Metallic Stent Versus Multiple Plastic Stents in Post Orthotopic Liver Transplantation Biliary Stenosis**

The recruitment status of this study is unknown because the information has not been verified recently.

Verified August 2012 by Hospital Israelita Albert Einstein.

Recruitment status was Recruiting

Sponsor:

Hospital Israelita Albert Einstein

Information provided by (Responsible Party):

FERNANDA PRATA MARTINS, Hospital Israelita Albert Einstein

ClinicalTrials.gov Identifier:
NCT01148199

First received: June 21, 2010

Last updated: August 31, 2012

Last verified: August 2012

[History of Changes](#)

[Full Text View](#)[Tabular View](#)[No Study Results Posted](#)[Disclaimer](#)[How to Read a Study Record](#)**► Purpose**

Biliary complications are one of the most common problems after orthotopic liver transplantation (OLT), occurring in up to 24% of patients.

Anastomotic strictures have been endoscopically managed with plastic stents placement. Recently, partially and fully covered metal stents have been alternatively used to treat refractory benign biliary stenosis. The investigators purpose is to compare efficacy and safety of metallic stents versus multiple plastic stents in the endoscopic management of post transplant biliary complications.

| Condition | Intervention | Phase |
|------------------------------|--|---------|
| Biliary Anastomotic Stenosis | Device: Self-expandable metallic stent | Phase 2 |
| Biliary Stricture | Device: Multiple plastic stents | Phase 3 |

Study Type: Interventional

Study Design: Allocation: Randomized

Endpoint Classification: Safety/Efficacy Study

Intervention Model: Parallel Assignment

Masking: Open Label

Primary Purpose: Treatment

Official Title: Self-expandable Metallic Stent Versus Multiple Plastic Stents in Post OLT Biliary Stenosis: Prospective, Randomized, Controlled Trial.

Resource links provided by NLM:

[MedlinePlus related topics: Liver Transplantation](#)

[U.S. FDA Resources](#)

Further study details as provided by Hospital Israelita Albert Einstein:**Primary Outcome Measures:**

- Post OLT biliary stricture resolution after stent removal [Time Frame: Up to 1 year] [Designated as safety issue: No]
Post OLT biliary stricture resolution will be evaluated during endoscopic stents removal up to 1 year after initial stents placement.

Secondary Outcome Measures:

- Sustained improvement after endoscopic treatment [Time Frame: 1 year after biliary stenosis resolution] [Designated as safety issue: No]
- Occurrence and severity of complications related to the endoscopic procedures [Time Frame: Up to 1 month]
[Designated as safety issue: Yes]
Occurrence and severity of complications after therapeutic ERCP will be evaluated and recorded up to 1 month after endoscopic procedures.

Estimated Enrollment: 64
Study Start Date: August 2009
Estimated Study Completion Date: October 2014
Estimated Primary Completion Date: September 2013 (Final data collection date for primary outcome measure)

| Arms | Assigned Interventions |
|--|--|
| Active Comparator: Multiple plastic stents | Device: Multiple plastic stents Comparison of self-expandable metallic stent versus multiple plastic stents in post OLT biliary stenosis. Other Names: <ul style="list-style-type: none">• Boston Scientific• Wilson Cook• Olympus |
| Experimental: Self-expandable metallic stent | Device: Self-expandable metallic stent Comparison of self-expandable metallic stent versus multiple plastic stents in post OLT biliary stenosis. Other Name: Wallflex, Boston Scientific |

Detailed Description:

Patients with biliary stricture after OLT will be randomly assigned following simple randomization to temporary placement of fully covered SEMS or multiple plastic stents placement were randomized according to a computer generated randomization sequence and allocated in a 1:1 ratio to one of two treatment groups.

Final success will be defined as clinical resolution of the stricture without the need to repeat endoscopic, percutaneous or surgical treatment.

► Eligibility

Ages Eligible for Study: 18 Years to 75 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria**Inclusion Criteria:**

- post-OLT biliary anastomotic stenosis (at least 1 month post-operative)
- jaundice, cholestasis and/or biliary tree dilation on US

Exclusion Criteria:

- biliary fistulae
- non-anastomotic stricture
- combine anastomotic and non-anastomotic stricture

► Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see [Learn About Clinical Studies](#).

Please refer to this study by its ClinicalTrials.gov identifier: NCT01148199

Contacts

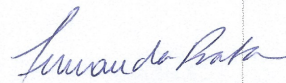
Contact: FERNANDA P MARTINS, MD +55 11 81936251 fernandapbm@gmail.com
Contact: ANGELO P FERRARI, MD +55 11 72833602 angelo@gastro.epm.br

Locations**Brazil**

Hospital Israelita Albert Einstein
Sao Paulo, SP, Brazil, 05652900
Contact: FERNANDA P MARTINS, MD +55 11 81936251 fernandapbm@gmail.com
Contact: ANGELO P FERRARI, MD +55 11 72833602 angelo@gastro.epm.br
Principal Investigator: FERNANDA P MARTINS, MD
Sub-Investigator: GUSTAVO A DE PAULO, MD

Sponsors and Collaborators

Hospital Israelita Albert Einstein

Investigators

Principal Investigator: FERNANDA P MARTINS, MD Hospital Israelita Albert Einstein
Study Chair: ANGELO P FERRARI, MD Hospital Israelita Albert Einstein

► More Information

Publications:

Mahajan A, Ho H, Sauer B, Phillips MS, Shami VM, Ellen K, Rehan M, Schmitt TM, Kahaleh M. Temporary placement of fully covered self-expandable metal stents in benign biliary strictures: midterm evaluation (with video). *Gastrointest Endosc*. 2009 Aug;70(2):303-9. Epub 2009 Jun 11.

Kahaleh M, Behm B, Clarke BW, Brock A, Shami VM, De La Rue SA, Sundaram V, Tokar J, Adams RB, Yeaton P. Temporary placement of covered self-expandable metal stents in benign biliary strictures: a new paradigm? (with video). *Gastrointest Endosc*. 2008 Mar;67(3):446-54.

Traina M, Tarantino I, Barresi L, Volpes R, Gruttadauria S, Petridis I, Gridelli B. Efficacy and safety of fully covered self-expandable metallic stents in biliary complications after liver transplantation: a preliminary study. *Liver Transpl*. 2009 Nov;15(11):1493-8.

Responsible Party: FERNANDA PRATA MARTINS, Attending phisician, Hospital Israelita Albert Einstein
ClinicalTrials.gov Identifier: [NCT01148199](#) [History of Changes](#)
Other Study ID Numbers: 1219-10
Study First Received: June 21, 2010
Last Updated: August 31, 2012
Health Authority: Brazil: National Committee of Ethics in Research

Keywords provided by Hospital Israelita Albert Einstein:
biliary anastomotic stricture
orthotopic liver transplantation
ERCP

Additional relevant MeSH terms:
Constriction, Pathologic
Pathological Conditions, Anatomical

ClinicalTrials.gov processed this record on November 12, 2014