ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: April 20, 2015

ClinicalTrials.gov ID: NCT01194843

Study Identification

Unique Protocol ID:	DPO-Hepatectomy
Brief Title:	Placebo-controlled Evaluation of Ropivacaine Efficacy by Local Infiltrations (DPO)
Official Title:	A Double-blind Placebo-controlled Evaluation of Ropivacaine Efficacy by Local Per and Post Hepatectomy Infiltrations for Adult Pain Management
Secondary IDs:	ET2007-073 [Registry ID: Centre Léon Bérard] 2007-007968-19 [EudraCT Number]

Study Status

Record Verification:	January 2014
Overall Status:	Completed
Study Start:	March 2009 []
Primary Completion:	February 2014 [Actual]
Study Completion:	April 2015 [Actual]

Sponsor/Collaborators

Sponsor:	Centre Leon Berard
Responsible Party:	Sponsor
Collaborators:	Centre Leon Berard AstraZeneca Fondation Apicil

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: A 08-99 Board Name: CPP (Comité de Protection des Personnes Board Affiliation: French Ministry of Health Phone: +33 478 78 27 61 Email: odette.maritaz@lyon.unicancer.fr Address:

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Data Monitoring: No

FDA Regulated Intervention: No

Study Description

Brief Summary: The purpose of the study is to evaluate the efficacy and impact on morphine consumption of ropivacaine administered by local per and post hepatic surgery infiltration.

Patients will be randomized to either ropivacaine or physiological serum, with equivalent administration modalities in both arms.

Patients will be followed during 4 days after the surgery. They will also come back for a follow-up visit one month later.

It is necessary to enrol 100 patients. The estimated period of inclusion is 24 months.

This is a prospective, comparative, monocentric, double-blind randomized study.

Detailed Description:

Conditions

Conditions: Hepatectomy
Pain
Metastasis

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Other

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Double (Participant, Investigator)

Allocation: Randomized

Enrollment: 85 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Ropivacaine Ropivacaine administration by local per and post surgery infiltration	Drug: Ropivacaine 40 ml infiltration at the end of the hepatectomy and then continuous local infiltration of 8 ml per hour over the 4 days after the hepatectomy
Active Comparator: Physiological serum	Drug: Physiological serum

Arms	Assigned Interventions
Administration of physiological serum by local per and post surgery infiltration	40 ml infiltration at the end of the hepatectomy and then continuous local infiltration of 8 ml per hour over the 4 days after the hepatectomy

Outcome Measures

Primary Outcome Measure:

1. Efficacy of ropivacaine versus physiological serum administered by local infiltration and impact on morphine consumption
   [Time Frame: In the 4 days following the hepatectomy]

Secondary Outcome Measure:

2. Efficacy of ropivacaine versus physiological serum administered by local infiltration and impact on daily morphine consumption
   [Time Frame: In the 4 days following the hepatectomy]
3. Evaluation of patients' perception of post-surgery pain
   [Time Frame: In the 4 days following the hepatectomy]
4. Immediate and late complications related to the perfusion, the medical device and other predictable side effects
   [Time Frame: In the 4 days following the hepatectomy and one month later]
5. Patients' post-surgery rehabilitation
   [Time Frame: Between surgery and follow-up visit, one month later]
6. Patients' satisfaction with the pain care
   [Time Frame: Four days after the hepatectomy]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Male or female patients aged ≥ 18 years
- Patients with histologically confirmed cancer
- Patients treated at the Centre Léon Bérard
- Patients requiring a surgery for hepatic metastases
- ASA <= 3
- At least 3 weeks between surgery and chemotherapy
- Total bilirubin < 1.5 x upper limit of normal range
- ASAT and ALAT < 5 times x upper limit of normal range
- Creatinine clearance > 60 ml per hour
- Serum creatinine < 115 µmol/l
- Mandatory affiliation with a health insurance system
- Patients able to understand French
- Signed, written informed consent

Exclusion Criteria:

- Patients with a hepatocellular carcinoma or an initial liver cancer
- Patients treated chronically by morphine
- Patients that already have abdominal pain

- Patients who are allergic either to morphinics, local anesthesics, paracetamol, NSAID or cortisone
- Patients suffering from heart, kidney or liver insufficiency
- Documented history of cognitive or psychiatric disorders
- Pregnant or lactating women
- Difficult follow-up

Contacts/Locations

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Study Principal Investigator
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IPDSharing

Plan to Share IPD:

References

Citations: Beaussier M, El'Ayoubi H, Schiffer E, Rollin M, Parc Y, Mazoit JX, Azizi L, Gervaz P, Rohr S, Biermann C, Lienhart A, Eledjam JJ. Continuous preperitoneal infusion of ropivacaine provides effective analgesia and accelerates recovery after colorectal surgery: a randomized, double-blind, placebo-controlled study. Anesthesiology. 2007 Sep;107(3):461-8. PubMed 17721249

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Links:

Available IPD/Information: