

# Ongoing Clinical Protocols at Ochsner

At any given time, between 600 and 800 active clinical trials are taking place at Ochsner Clinic Hospital. A selected few are listed here. If you have patients meeting the listed criteria for a given trial, please call the contact numbers for more information on enrollment. For more information about Ochsner's research programs, please call Ochsner Research Administration at 504 842-3265.

## Anticoagulation

**Sponsor:** Aventis Pharmaceuticals  
**Investigator:** Steven Deitelzweig, MD  
**Contact:** Patricia Schaefer, RN, CCRC 504 842-5098

### Title:

**Bridging Registry: clinical outcomes with the use of unfractionated heparin or low-molecular-weight-heparin as perioperative and periprocedural bridging therapy in patients on long-term oral anticoagulant treatment requiring interruption for an elective procedure (surgical or medical).**

### Study Objective:

To evaluate and compare clinical outcomes of patients on coumadin requiring perioperative bridging for an elective procedure or elective surgery. Two patients groups will be compared: patients receiving unfractionated heparin and patients receiving low-molecular-weight-heparin in the perioperative period, either in a hospital or outpatient setting.

### Inclusion Criteria

- 18 years or older
- A major or minor surgical intervention or procedure necessitating temporary discontinuation of oral anticoagulant therapy
- On oral anticoagulant therapy for > 3 months prior to the procedure
- Heparin (in any form) was given as a bridge to oral anticoagulant therapy either in the preoperative or postoperative period or both, for 2 or more days

### Exclusion Criteria

- Patients enrolled in another bridging study or trial within 30 days
- Patients without any form of heparin used as a bridge (i.e. discontinuation of oral anticoagulant therapy with tranexamic acid for a dental procedure)

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## Venous Thromboembolism Prophylaxis

**Sponsor:** Aventis Pharmaceuticals  
**Investigator:** Steven Deitelzweig, MD  
**Contact:** Patricia Schaefer, RN, CCRC 504 842-5098

### Title:

**EXCLAIM - LOVENOX: A double-blind, placebo controlled, parallel, multicenter study on extended VTE prophylaxis in acutely ill medical patients with prolonged immobilization**

### Study Objective:

To compare extended venous thromboembolism prophylaxis with enoxaparin 40 mg sc qd for 28 ± 4 days with placebo, both following 10 ± 4 days of initial treatment with enoxaparin 40 mg sc qd.

### Inclusion Criteria:

- 40 years or older
- Recent immobilization ( $\leq 3$  days)
- Anticipated immobilization of  $6 \pm 2$  days with a level of activity 1 and 2 at the time of study entry and likely to continue at this level of immobilization after the initial  $6 \pm 2$  day period
- Mean hemoglobin  $<10$  g/dL on two consecutive occasions
- Presence of at least one of the following medical conditions:
  1. Heart Failure, NYHA class III and IV
  2. Acute respiratory insufficiency defined by abnormal functional respiratory tests, without immediate need for ventilatory support
  3. Other acute medical conditions, such as:
    - Status post acute ischemic stroke (within 72 hrs after occurrence) diagnosed by objective methods (CT or MRI)
    - Acute infection without septic shock
    - Acute rheumatic disorder
    - Active episode of inflammatory bowel disease
    - Active cancer
  4. Anticipated survival time of  $\geq 6$  months

### Exclusion Criteria:

- Women pregnant or of childbearing age not using effective contraception
  - Patients with any evidence of an active bleeding disorder
  - Contraindication to anticoagulation
  - Major surgery within the previous 3 months
  - Patients who have had spinal or epidural analgesia or lumbar puncture within the preceding 24 hours
  - Cerebral stroke with bleeding
  - Patients with confirmed cerebral metastases
  - Known hypersensitivity to heparin or LMWH, or pork derived products
  - History of documented episode of heparin or LMWH induced thrombocytopenia and/or thrombosis (HIT, HAT, or HITTS)
  - Patients with a persistent renal failure
  - Known or suspected severe anemia of unexplained cause
  - Patients with prosthetic heart valves
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