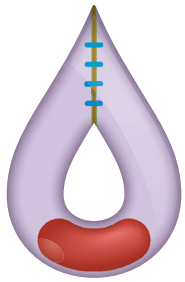
# ARTS Trial — A Large, Pragmatic, International Trial of Thromboprophylaxis in General Abdominal, Gynecologic, and Urologic Surgery



**ARTS**
Avoiding Risks of Thrombosis and Bleeding in Surgery
A randomized trial by CLUE

### STUDY DESIGN AND ELIGIBILITY

- Pragmatic trial of 5,436 patients
- Randomized, open-label
- Adult patients undergoing abdominal or pelvic surgery at similar risks of VTE and bleeding
- Centers able to choose from which eligible procedures they recruit patients

### RANDOMIZATION

- Randomization (1:1) to a direct oral anticoagulant (apixaban) or no anticoagulant using online randomization system
- Performed at earliest 12 hours post-surgery or at latest next noon on post-operative day

### FOLLOW-UP

- No extraneous data collection
- 90 days follow-up

**Experimental Arm**
Local standard of care mechanical thromboprophylaxis +

**Apixaban 2.5 mg orally twice daily for 4 weeks**

**Comparator Arm**
Local standard of care mechanical thromboprophylaxis +

**No anticoagulation**

### PRIMARY OUTCOME

- Venous thrombo-embolism (VTE), defined as symptomatic deep vein thrombosis (DVT), or symptomatic non-fatal or fatal pulmonary embolism (PE)

### SAFETY OUTCOMES

- Major bleeding, defined as bleeding leading to a postoperative hemoglobin <70 g/L, transfusion of ≥1 unit of red blood cells, or bleeding that was judged to be the immediate cause of death
- Bleeding requiring re-intervention or endovascular embolization to stop bleeding

CLUE
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