

LEAP Pilot: **L**ow Molecular Weight **H**eparin vs. **A**spirin **P**ostpartum

Evangelia Vlachodimitropoulou MBBS Ph.D., Kinga Ann Malinowski MD MSc FRCSC, Eric Kaplovitch MD FRCPC, Ravnit Lomash BDS, Kellie Murphy MD MSc FRCSC, Nadine Shehata MD, MSc, FRCPC
Mount Sinai Hospital, Toronto, Canada



BACKGROUND

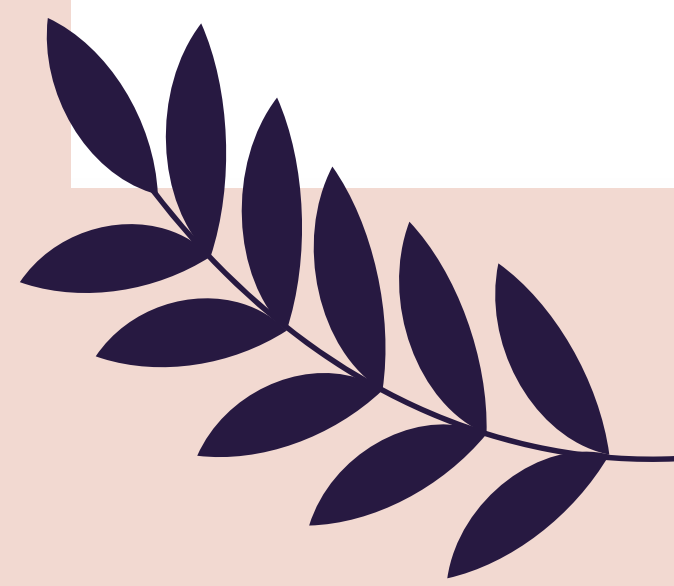
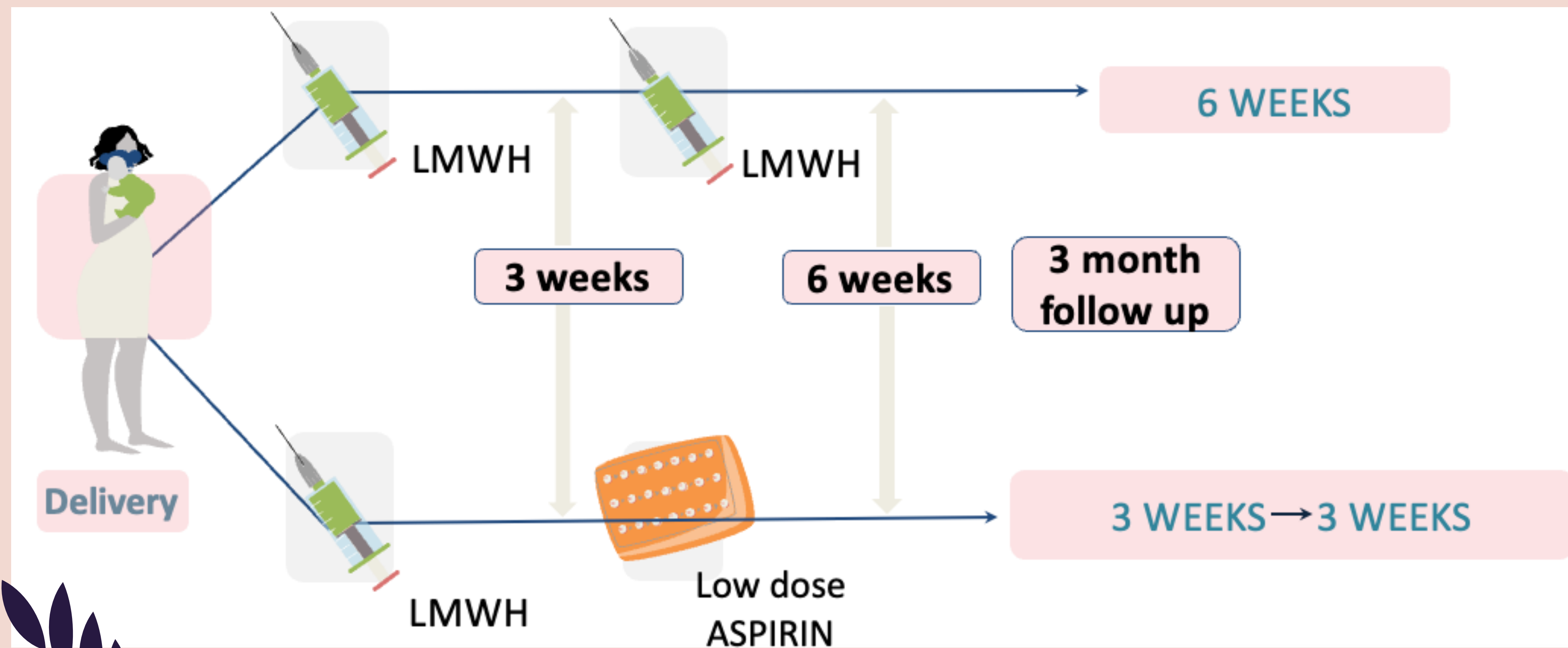
The highest risk period for VTE in all postpartum women is between 1-3 weeks, with a sharp decline documented following this time period. The incidence reduces from 9.41/10,000 in the 1st week to 1.00/10,000 in the 4th week.

A 2021 **Cochrane review** concluded that there is **insufficient evidence on which to base thromboprophylaxis in the pregnancy postpartum setting, and high-quality randomized trials are warranted.**

AIM

The principal question to be addressed, in a large definitive trial, is whether sequential administration of low molecular weight heparin (LMWH) for 3 weeks followed by low dose aspirin for 3 weeks is non-inferior to standard of care of 6 weeks LMWH for VTE prophylaxis postpartum. This is a single-center randomized pilot feasibility study to address enrollment and adherence.

STUDY DESIGN



INCLUSION CRITERIA

History of VTE, not taking therapeutic extended anticoagulation

Family hx of VTE + Antithrombin/Protein C or Protein S deficiency

Combined thrombophilia or homozygous factor V Leiden/ homozygous prothrombin gene mutation

EXCLUSION CRITERIA

Therapeutic anticoagulation

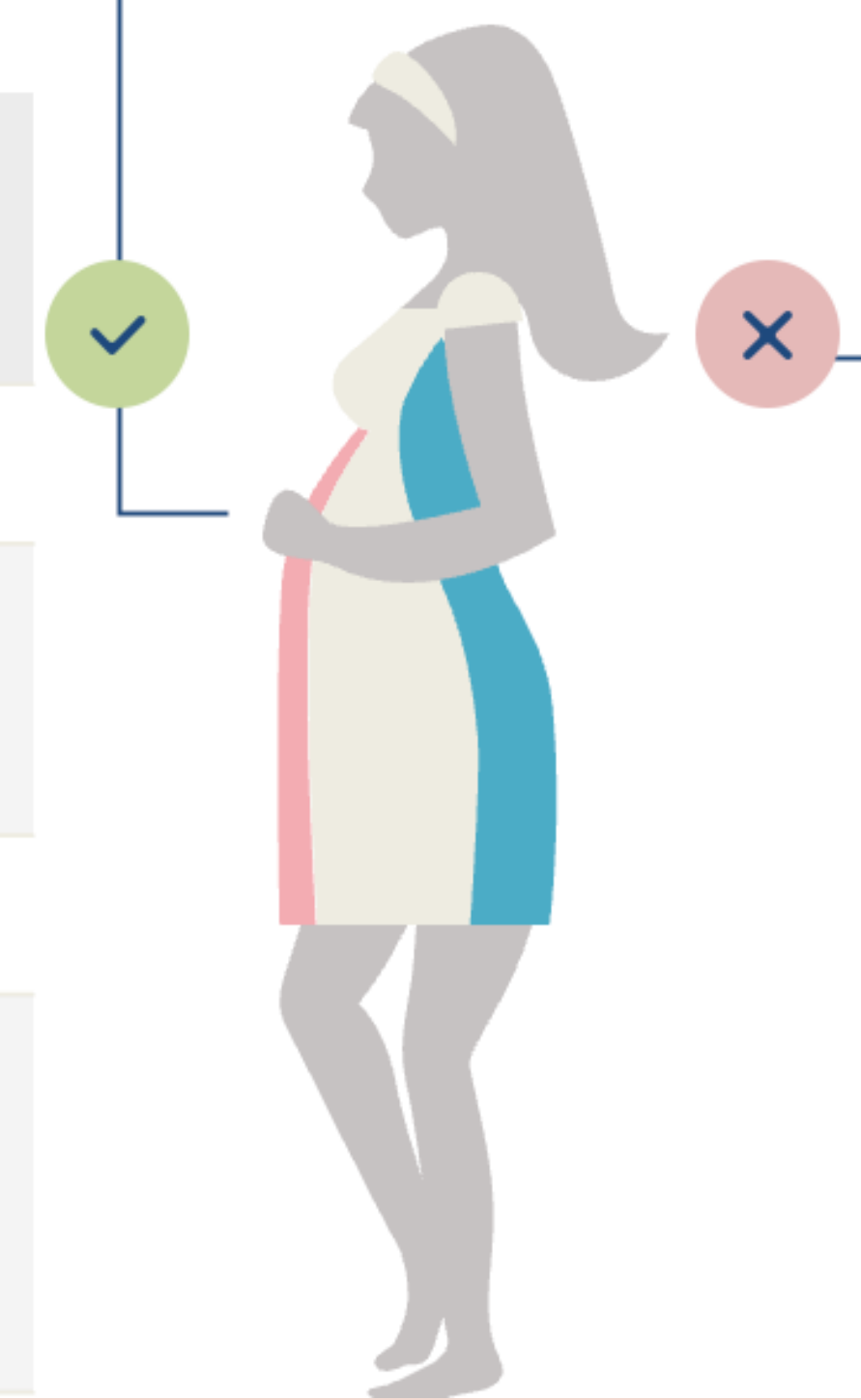
Aspirin/LMWH contraindication

Platelets < 50 x 10⁹/L

Bleeding disorders

Severe hypertension

Sickle cell disease/APS/MPN



RESULTS

Recruitment period: Jan 2022- April 2023

Total eligible: 57 (1 per week)

Total approached: 46 (2 pending decision)

Total enrolled: 22/44

Recruitment rate: 50%

Completion of 3 and 6 week follow-up: 17/22

Adherence: Aspirin arm 97.3%, LMWH arm 97.4%

Bleeding: Aspirin arm and LMWH arm - 2x minimal gingival bleeding.

Quality of life score: 35% better in the Aspirin arm vs the LMWH arm. 51% improvement following switch to Aspirin from LMWH after the first 3 weeks.

CONCLUSIONS

Recruitment rate is currently 50%.

Compliance is similar in the Aspirin and in the LMWH arm.

No thrombosis has been noted.

No severe bleeding complications.

Quality of life shows an improving trend in the Aspirin arm.

NEXT STEPS

Extend to a multicenter pilot to address enrollment, adherence and feasibility.