

Randomized Evaluation of Bromocriptine In Myocardial Recovery Therapy (REBIRTH) for Peripartum Cardiomyopathy

What is Peripartum Cardiomyopathy (PPCM)?

Peripartum cardiomyopathy (PPCM) is a rare complication of pregnancy with a good prognosis for many but there is a high rate of adverse events and mortality among those with LVEF $\leq 35\%$. Bromocriptine is used in Europe for possible myocardial recovery based on a few clinical trials but there are still questions about its use.

What is the purpose of this study?

The objective of REBIRTH is to determine the impact of bromocriptine therapy on myocardial recovery and subsequent clinical outcomes in a placebo controlled double blind randomized trial. There is evidence the earlier the treatment with bromocriptine, the more likely patients are to recover. Those not in the randomized trial who meet all inclusion and exclusion criteria who are breastfeeding may participate in a breastfeeding cohort.

REBIRTH Key Points

Study Population

200 women with a recent diagnosis of PPCM who are 18 years or older, within 5 months postpartum and not breastfeeding. Women who breastfeed may be eligible for participation in a breastfeeding cohort.

Study Drug

Bromocriptine or placebo for 8 weeks. If not on clinical anticoagulation, participants will also receive rivaroxaban or placebo for 8 weeks while on bromocriptine or placebo.

Study Sites

Approximately 50 sites at tertiary referral centers across the United States and approximately 3 sites in Canada are recruiting.

Patient Experience

Study Visits

- Entry study visit lasts approximately 2-2.5 hours
- Follow up visits at Month 1, Month 3, Month 6, Month 12 last approximately 1-1.5 hours
- Follow up visits at Month 24 and Month 36 can be done in-person or remotely
- Duration of participation: Approximately 3 years

Visit Procedures May Include:

- Clinical assessment
- Medical history
- Research blood draw for biomarkers
- Echocardiogram
- Questionnaires
- Study drug accountability

