Acute improvement in hemodynamic control after osteopathic manipulative treatment in the third trimester of pregnancy

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PROMOTE study

Pregnancy Research in Osteopathic Manipulation Optimizing Treatment Effects
NIH (NCCAM) study design
(part of K23 grant)
STUDY ONE HYPOTHESIS
OMM improves selected clinical outcomes in pregnancy.
48 months, 400 subjects, prospective, randomized, blinded clinical trial

STUDY TWO HYPOTHESIS
Physiological changes related to improved autonomic and peripheral hemodynamic regulation are, in part, responsible for the hypothesized clinical effects of OMM in Study One.
24 months, 100 subjects, random selection from the first 200 subjects in Study One

STUDY THREE HYPOTHESIS
Biomechanical changes related to improved gait are, in part, responsible for the hypothesized clinical effects of OMM in Study One.
24 months, 100 subjects, random selection from the first 200 subjects in Study One

- LOW BACK PAIN
- FUNCTIONAL STATUS
- MECONIUM-STAINED AMNIOTIC FLUID

AUTONOMIC MEASURES
HEMODYNAMIC MEASURES
GAIT MEASURES
NIH/AOA Physiology Substudy

• Before and after treatment
  • 30 weeks gestation
  • 36 weeks gestation

• Autonomic and hemodynamic measures
  • Heart rate variability
  • Blood pressure variability
  • Leg volume
  • Supine venous flow rate
  • Orthostatic challenge and skeletal muscle pump as physiologic stimuli
Substudy Protocol

- Subject on circlebed at 10°
- Leg measurements
- Application of leads
  - EKG
  - Strain gauge
  - Finometer
- 15 minutes at rest
- Tilt to 60°

- Rest 5 minutes
- Heel raises for 4 minutes
  - 2s up, 3s down
- Rest 3 minutes
- Move to treatment room for study treatment
- Repeat physiologic measures
Baseline (15 min) → Tilt (5 min) → Tilt and heel raise (4 min)

Δ Tilt effect

Δ Heel raise effect
Data will be discussed here in presentation
What’s next?

- Manuscript in press in Complementary Therapies in Medicine
- Clinical data submitted and in revision
- Using this study to teach research competencies to students, residents and physicians
- Training ACOOG residents in protocol, as well as DOs and MDs
- Expanding collaborations with ACOOG to develop larger, multi-center study
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