

RCT of Prenatal Choline Supplementation During Pregnancy to Mitigate Adverse Effects of Prenatal Alcohol Exposure

NCT04395196

Status	RECRUITING
Phase	Phase 2
Sponsor	Wayne State University
Enrollment	288 participants

Plain Language Summary

This study tests whether taking choline supplements during pregnancy can reduce the harmful effects of alcohol on fetal brain development. It is aimed at pregnant women in South Africa who drink alcohol during pregnancy, a setting where fetal alcohol spectrum disorder is a serious public health concern.

****You may be eligible if...****

- You are 18 or older
- You are 20 weeks pregnant or less, with a single baby
- You have been drinking heavily during your pregnancy (averaging at least 15 ml of pure alcohol per day, or binge drinking regularly)
- Your current choline intake from food is less than 1 gram per day
- You speak English or Afrikaans

****You may NOT be eligible if...****

- You are using methamphetamine or other illicit drugs (except marijuana) in the past year
- You are HIV positive
- You have a serious pre-existing medical condition requiring medication (such as diabetes, epilepsy, heart disease, or high blood pressure)
- A child of yours has already been enrolled in this study from a previous pregnancy
- You plan to move away from the area before the study is complete

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (6)

- Age e18 yr
- d20wk gestation
- Singleton pregnancy
- Currently heavy drinking (average of e15 ml AA/day or binge drinking (e4 standard drinks/occasion) on at least 1.5 occasions/month on average since becoming pregnant)
- Current choline dietary intake \<1 g/day
- ... and 1 more (see full listing online)

Exclusion (5)

- Use of methamphetamine or other illicit drugs other than marijuana during the past year
- HIV positive
- Pharmacologic treatment for a serious pre-existing medical condition (e.g., diabetes, hypertension, epilepsy, or cardiac problems)

<https://clinicaltrials.gov/study/NCT04395196>

- Having another child enrolled in the trial from a previous pregnancy

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).

- Plans for mother or child to move away from the area prior to study completion

Locations (1 total)

University of Cape Town Faculty of Health Sciences, Cape Town, Western Cape, South Africa