

Expecting and Excluded:

Assessing the inclusion of pregnant women in pharmacological trials

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Background

- **Almost all pregnant women require medication**
 - Up to 97% use at least one medication, and 30% use five or more.^[1]
- Adequate **data on drug efficacy and safety in pregnancy is lacking in over 90% of medications used in pregnancy.**^[2]
- **Pharmacological trials specifically designed for the pregnant population are underrepresented, accounting for only 0.32% of clinical trials globally**
 - This proportion is substantially lower than other clinical areas of comparable incidence of disease, or healthcare cost.^[3]
- It is unclear how often pregnant women are included in general medication trials (that is, those not specifically designed for the pregnant population).

Methods

- **Three clinical trial registries (Clinicaltrials.gov, the European Union Clinical Trials Register and the Australia and New Zealand Clinical Trials Register) were searched** for trials conducted from 2023-2024 including women of child-bearing age in the following **therapeutic areas: antibiotics, antihypertensives, and antidiabetics.**
- The study protocol of each eligible trial was examined to determine if pregnancy was an exclusion criteria.
- Trials were excluded if: they involved medications known to be teratogenic, if the comparator was surgical management, or if they concerned age-related diseases uncommon in women of child-bearing age.

We aimed to **examine the frequency with which pregnant women are eligible for inclusion in medication trials performed in selected therapeutic areas relevant to pregnancy** in order to provide current data on the relative underrepresentation of pregnant participants.



543 relevant trials of antibiotics, antihypertensives and antidiabetics were performed from 2023-2024

18 (3.3%) did NOT exclude pregnant participants

Of which:

- **13** were **pregnancy-specific** trials
- **5** were **general population** trials (non-pregnancy-specific)

Table 1: Characteristics of general population trials that did not exclude pregnant participants

Trial title	Therapeutic area	n=	Phase
BEAT CF: Pulmonary Exacerbations Treatment Platform - Adjunct Antibiotics Domain	Antibiotics	Enrolment ongoing	Phase 4
A Randomised Control Trial to compare the infection rate of topical use of antibiotic vs conventional management of open fractures.	Antibiotics	= 120	Phase 1
The effect of Calcium Hydroxide, Triple Antibiotic Paste and Chlorhexidine on pain in teeth with Symptomatic Apical Periodontitis	Antibiotics	= 80	Phase 4
Optimising postprandial glycaemia in adolescents and adults with Type 1 diabetes using Closed Loop Insulin Delivery.	Diabetes	Enrolment ongoing	Phase 4
Establishment of an insulin dosing schedule for high fat, high protein meals in individuals with type 1 diabetes using insulin pump therapy.	Diabetes	Enrolment ongoing	Phase 4

Conclusions

- **Pregnant women are underrepresented in trials of antibiotics, antihypertensives and antidiabetics, with the overwhelming majority of general medication trials listing pregnancy as an exclusion criterion.**
- Only a small proportion of trials in these therapeutic areas are specifically dedicated to examining a pregnant population.
- Notably, in each of the therapeutic categories surveyed in this study there are existing medication options known to be safe in pregnancy, which may partly account for the widespread exclusion of pregnant women from these trials. Further research is needed to establish the relative representation of pregnant women in medication trials in other therapeutic areas with fewer existing safe options for pregnancy.
- **There is a need for further advocacy, incentives, and policy change to increase the inclusion of pregnant women in medication trials, and to address the present lack of data on medication safety in pregnancy.**

References
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