

Maternal hypotension during elective caesarean delivery under various spinal anaesthesia regimens

ACTRN12616000884404

Status	RECRUITING
Phase	Phase 4
Sponsor	University Hospital Gregorio Maranon
Enrollment	280 participants

Plain Language Summary

This trial is testing different combinations of medications to prevent a dangerous drop in blood pressure (hypotension) that commonly occurs during spinal anaesthesia for a planned caesarean section. The four options being compared are: a placebo, ondansetron (a nausea drug), a continuous infusion of phenylephrine (a blood pressure drug), and a combination of both ondansetron and phenylephrine. Researchers want to find the most effective way to keep the mother's blood pressure stable during the operation.

You may be eligible if:

- You are a woman between 20 and 45 years old
- You are scheduled for an elective (planned) caesarean section under spinal anaesthesia
- You are classified as ASA (American Society of Anesthesiologists) physical status class 1 (healthy)
- Your BMI at delivery is 30 or less
- You are able to give written informed consent

You may NOT be eligible if:

- You refused to participate
- You have a contraindication to spinal anaesthesia
- You are under 20 or over 45 years old
- Your BMI exceeds 30 kg/m² at the time of surgery
- You have previously received intravenous fluids before the procedure
- You have a known allergy or reaction to ondansetron or phenylephrine

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (2)

- American Society of Anaesthesiologists class I women scheduled for lower segment caesarean delivery under spinal anaesthesia enrolled during anaesthesia consultation or early in the third trimester.
- Written informed consent must be obtained from all patients to participate in this study.

Locations (1 total)

Madrid, Spain

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12616000884404>

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