

FB-CT2 Includes Two Prospective, Multi-centre Studies With a Medical Device in Hospital Settings: a Randomized, Dual-arm, Open-label Pilot Study in Spain, Followed by a Single-arm, Non-randomized, Open-label International Pivotal Study

NCT06968364

Status	RECRUITING
Phase	Not Applicable
Sponsor	Ultrasound-Innovation Medtech, S.L.
Enrollment	457 participants

Key Eligibility Criteria

Inclusion (7)

- Female e18 years
- Singleton pregnancy
- Live fetus, 28w+0d-36w+6d GA
- Intact membranes
- Cervical dilatation \leq 2 cm
- ... and 2 more (see full listing online)

Exclusion (12)

- Latex allergy
- Prolapsed membranes
- Fetal malformation
- Fetal infection
- Vaginal bleeding (severe or persistent)
- ... and 7 more (see full listing online)

Locations (14 total)

- H. Universitario de A Coruña, A Coruña, Spain
- H. Clínic de Barcelona, Barcelona, Spain
- H. Sant Joan de Déu, Barcelona, Spain
- ... and 11 more locations

<https://clinicaltrials.gov/study/NCT06968364>

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