

IBP-9414 for the Prevention of Necrotizing Enterocolitis - The Connection Study

Status: OPEN TO ACCRUAL

Eligibility Criteria

Age: Up to 48 hours old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

- Gestational age at birth of 23 weeks+0 days to 32 weeks+0 days
- Birth weight 500-1500g
- ? 48 hours of age
- Written informed consent from the subject?s legally authorized representative (LAR)

Exclusion Criteria:

- Participation in any other interventional clinical trial
- Infants in extremis to whom no further intensive care is offered by attending neonatologist
- Infants with, or at a high probability for, early onset sepsis
- Infants with recognized chromosomal anomalies
- Congenital or acquired gastrointestinal disease
- Earlier or planned administration of formulas, foods or supplements that contain added live bacteria
- Infants with known positive maternal HIV status

Conditions & Interventions

Interventions:

Drug: IBP-9414, Drug: Placebo, drug: lbp-9414

Conditions:

Necrotizing Enterocolitis, Certain Conditions Originating in the Perinatal Period (760-779)

More Information

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Principal Investigator: Moores, Russell, Ray

Phase: III

IRB

Number: HM20018843

System ID: NCT03978000

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