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Trial record **2 of 4** for: anabrees

Previous Study | Return to List | Next Study

Glycerin Suppositories for Treatment of Feeding Intolerance in Preterm Infants

This study is currently recruiting participants. (see Contacts and Locations)

Verified May 2014 by King Saud Medical City

Sponsor:
King Saud Medical City

Collaborator:
Sulaiman Al Habib Medical Group- Arrayan Hospital

Information provided by (Responsible Party):
King Saud Medical City

ClinicalTrials.gov Identifier:
NCT02149407

First received: May 20, 2014
Last updated: May 25, 2014
Last verified: May 2014
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

Feeding intolerance is a common problem in preterm infants.

Condition	Intervention
Feeding Intolerance	Drug: Glycerin Procedure: Rectal stimulation Other: Control

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Efficacy and Safety of Glycerin Suppositories for Treatment of Feeding Intolerance in Very Low Birth Weight Infants

Resource links provided by NLM:

MedlinePlus related topics: Premature Babies

Drug Information available for: Glycerin

U.S. FDA Resources

Further study details as provided by King Saud Medical City:

Primary Outcome Measures:

- Time to full feeding (days) [Time Frame: Participants will be followed for the duration of hospital stay, an expected average of 3 weeks] [Designated as safety issue: No]

  Days to achieve full enteral feeding

Secondary Outcome Measures:

- Incidence of feeding intolerance [Time Frame: Participants will be followed for the duration of hospital stay, an expected average of 4 weeks] [Designated as safety issue: No]

  Feeding intolerance defined as feeding withheld, discontinued, or decreased because the infant was not tolerating enteral feedings.

- Incidence of necrotizing enterocolitis (NEC) [Time Frame: Participants will be followed for the duration of hospital stay, an expected average of 8 weeks] [Designated as safety issue: No]

  Necrotizing enterocolitis (NEC) defined as per Bell's staging.

- Incidence of proven late onset infection [Time Frame: Participants will be followed for the duration of hospital stay, an expected average of 8 weeks] [Designated as safety issue: No]

  Incidence of proven late onset infection defined as clinical signs in addition to positive blood culture beyond 72 hours of age.

- Incidence of hyperbilirubinemia [Time Frame: Participants will be followed for the duration of hospital stay, an expected average of 8 weeks] [Designated as safety issue: No]

  Incidence of hyperbilirubinemia defined as level of bilirubin requiring treatment with phototherapy according to the bilirubin chart used in the participating unit.

- Length of hospital stay (days) [Time Frame: At discharge from hospital, an expected average of 8 weeks] [Designated as safety issue: No]

Other Outcome Measures:

- Growth at discharge from hospital [Time Frame: At discharge from hospital, an expected average of 8 weeks] [Designated as safety issue: No]

  Growth parameters at discharge from hospital include: Weight (grams), Length (cm), and Head circumference (cm)

- Retinopathy of prematurity (ROP) [Time Frame: Participants will be followed for the duration of hospital stay, an expected average of 8 weeks] [Designated as safety issue: No]

  Defined by the International Classification of Retinopathy of Prematurity (ICORP)

- Bronchopulmonary dysplasia (BPD) [Time Frame: Participants will be followed for the duration of hospital stay, an expected average of 8 weeks] [Designated as safety issue: No]
- Patent ductus arteriosus (PDA) [Time Frame: Participants will be followed for the duration of hospital stay, an expected average of 8 weeks] [Designated as safety issue: No]

  Diagnosed by echocardiogram

- Side effects [Time Frame: Participants will be followed for the duration of hospital stay, an expected average of 8 weeks] [Designated as safety issue: Yes]

  For example: Rectal bleeding, Rectal Perforation, or Hematochezia

Estimated Enrollment:	230
Study Start Date:	May 2014
Estimated Study Completion Date:	August 2016
Estimated Primary Completion Date:	May 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Glycerin group (GG) Glycerin group "GG" will receive the 0.5 suppository (700 mg) twice daily for 48 hours. We will use the rounded part and discard the other part then will hold baby's buttocks for 2 minutes to ensure its delivery.	Drug: Glycerin Glycerin group "GG" will receive the 0.5 suppository (700 mg) twice daily for 48 hours. We will use the rounded part and discard the other part then will hold baby's buttocks for 2 minutes to ensure its delivery. Other Name: Glycerine
Active Comparator: Rectal stimulation group (SG) Rectal stimulation "SG" by soft cotton swab inserted to around 3 cm. The stick will press against the rectal wall in all direction for 2 minutes twice daily for 48 hours. Ky gel will be used to lubricate the stick and minimize direct friction to rectal wall.	Procedure: Rectal stimulation Rectal stimulation "SG" by soft cotton swab inserted to around 3 cm. The stick will press against the rectal wall in all direction for 2 minutes twice daily for 48 hours. Ky gel will be used to lubricate the stick and minimize direct friction to rectal wall.
Sham Comparator: Control group (CG)	Other: Control

Control group "CG" will receive routine NICU medical care without any specific intervention for the infant. The research nurse will do shame placebo twice daily by opening his diaper to blind the team for 2 minutes.	Control group "CG" will receive routine NICU medical care without any specific intervention for the infant. The research nurse will do shame placebo twice daily by opening his diaper to blind the team for 2 minutes.

Eligibility

Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria
Inclusion Criteria:

- Preterm infants with birth weight equal or less than 1500 g

Exclusion Criteria:

- Significant congenital malformations
- Severity of illness such that death is likely in the first few days after birth

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02149407

Contacts

Contact: Jasim **Anabrees** jasim1800@yahoo.com

Locations

Saudi Arabia

King Saud Medical City **Recruiting**
Riyadh, Saudi Arabia
Contact: Latifa Almahmoud latifa369@yahoo.com
Principal Investigator: latifa Almahmoud
Sub-Investigator: Haider Somaily
Sub-Investigator: Nabeel Al-Odaisan
Sub-Investigator: Sadia Al-Shehri

Sulaiman Al Habib Medical Group **Not yet recruiting**
Riyadh, Saudi Arabia
Contact: Jasim **Anabrees**, FRCPCH jasim1800@yahoo.com
Principal Investigator: Jasim **Anabrees**, FRCPCH

Sponsors and Collaborators

King Saud Medical City

Sulaiman Al Habib Medical Group- Arrayan Hospital

More Information

No publications provided

Responsible Party: King Saud Medical City
ClinicalTrials.gov Identifier: NCT02149407 History of Changes

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Study First Received: May 20, 2014
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Health Authority: Saudi Arabia: Ministry of Health

Additional relevant MeSH terms:

Glycerol
Cryoprotective Agents
Protective Agents
Physiological Effects of Drugs
Pharmacologic Actions

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