What is the purpose of the study?
The purpose of this study is to observe how babies respond to and tolerate an investigational formula. An investigational formula is one not yet evaluated by the U.S. Food and Drug Administration (FDA). The type of formula in this study is a discharge formula. Discharge formulas are intended to be used by premature infants after discharge from the hospital. Although discharge formulas are started in the hospital, they are mainly used to feed the preterm infant at home. Discharge formulas have higher levels of energy (calories) and protein than standard term infant formulas but are not as high in calories, protein and other nutrients as the preterm formulas used in the hospital.

Who is eligible to participate in the study?
Preterm infants born at Advocate Lutheran General Children’s Hospital who are nearly ready for hospital discharge and are being fed only formula (no breast milk) may be eligible to participate in this study.

What does the study involve?
Infants in this study will be randomized (that is, by chance, like the flipping of a coin) to one of 2 formula groups. Half of the babies will receive the investigational formula and the other half of the babies will receive the formula which is currently available at stores and through pediatrician offices. This study is a double-blinded study, meaning that neither the parents nor the researchers will know which formula the infant participants are consuming. The researchers will compare the two groups on how well the babies grow and tolerate the formula. The two formulas used in this study contain nutrients in amounts intended for full nutritional support of premature infants after discharge from the hospital. Caregivers will be asked to feed the baby the assigned formula whenever (s)he is hungry upon discharge from the hospital. There are no specific instructions to follow on feeding amounts or schedules. Both of the formulas will be provided in the ready-feed (liquid) form.

The baby’s medical history and growth measurements will be collected while (s)he is in the hospital. Information about the baby’s mother will be collected, including date of birth, years of education, number of pregnancies and number of live births. The researchers will also monitor the baby’s tolerance of the assigned formula from the day of study enrollment, through day of hospital discharge. The baby will have one blood draw for study lab work within 3 days of discharge and at out-patient visits 2 and 5. The baby will follow-up at the out-patient clinic for 6 visits after hospital discharge. At the clinic visits, the baby will be weighed and measured and the research staff will ask about the baby’s health since the last visit. In addition caregivers will need to keep a detailed record (a diary) of information about the baby for the 2 days just before the clinic visit. This information will include how much formula the baby drinks, what the baby’s bowel movements are like, and the baby’s behavior.

The study will last about 6-8 months depending on the gestational age of the baby at birth (meaning how premature the baby was born).

What are the benefits?
There is no direct benefit to participating in the study. Information gained in the study will be used in an effort to make infant formulas better for babies in the future.
What are the risks?
The research study team will discuss all risks with interested participants prior to enrolling in the study.

Is there any compensation for participating?
Participants will receive $20 for each out-patient clinic visit attended to defer transportation costs.

How will I get more information about the study?
Interested parents will discuss the study with a member of the research team and will be given a parental permission/consent form that further explains all of the details of the study. Study procedures will not be started until the parent(s) fully understands what is involved in the study and has signed a parental permission/consent form.

Status: Recruiting
Site(s): Advocate Lutheran General Children’s Hospital

Who should I contact for more information?
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