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Routine gastric residual aspiration in preterm infants and the effect on reaching full feed

Submission date
19/12/2017

Recruitment status
No longer recruiting

Registration date
15/01/2018

Overall study status
Completed

Last Edited
22/06/2023

Condition category
Neonatal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Enteral nutrition is a way to provide food through a tube placed in the nose, the stomach, or the small intestine. Gastric residual (GR) refers to the volume of fluid remaining in the stomach at a point in time during enteral nutrition feeding. It is routinely evaluated in preterm infants fed through a tube (routine GR aspiration). Not only there is no evidence to justify the use of the routine practice of GR aspiration, there is also no standard management of the GR. There are wide variations amongst neonatologists and between different neonatal intensive care units (NICUs) regarding the significance of the volume and color of the GR and the interval at which the GR should be checked. Nutrition in the NICU is considered one of the most challenging and important aspects of neonatal care to optimize the clinical outcomes of this fragile and at risk population. Routine GR aspiration can delay the achievement of full enteral feeding with its consequences of extra-uterine growth retardation, cholestasis and increased risk of sepsis. The aim of this study is to evaluate the effect of routine GR aspiration in preterm infants on reaching feed of 120cc/kg/day. It is thought that infants not receiving routine GR evaluation would reach a feed of 120cc/kg/day 3 days earlier than infants undergoing routine GR aspiration.

Who can participate?
Preterm infants at 32 weeks gestation or less

What does the study involve?
Participants are randomly allocated to one of two groups. Both groups strictly follow the feeding protocol as per the unit protocol. Infants in one group undergo routine gastric aspiration with pre-feeding aspiration every 6 hours. Infants in the other group proceed with feeding with no aspiration. Both groups strictly follow a scheme in case of having vomiting, abdominal distension or other GI symptoms. The number of days it takes to reach a feed of 120cc /kg/day is recorded. All infants are followed up until discharge.

What are the possible benefits and risks of participating?
Based on previous studies, patients not receiving routine GR aspiration may reach a full feed 6 days earlier and have fewer 6 days on central line. Possible risks include regurgitation and vomiting in the no aspiration group.

Where is the study run from?
King Abdulaziz University Hospital (Saudi Arabia)

When is the study starting and how long is it expected to run for?
December 2015 to December 2019

Who is funding the study?
King Abdulaziz University (Saudi Arabia)

Who is the main contact?
Dr Hala Aljariry
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HA-02-J-008

Study information

Scientific Title
Routine gastric residual aspiration in preterm infants and the effect on reaching full feed: a randomized controlled trial

Study objectives
It is hypothesized that infants not receiving routine gastric residual (GR) evaluation would reach feed of 120cc/kg/day 3 days earlier than infants undergoing routine GR aspiration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee at King Abdulaziz University, 20/12/2015, ref: 396-15

Study design
Single-center unblinded randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Reaching full feed

Interventions
Prior to the experiment, a pilot study of 40 subjects was ran to obtain the variance estimates needed in determining the sample size. With the existing feeding protocol in the unit, the average time for infants less than or equal to 32 weeks to reach 120 ml/kg/day of feeding was 12 days (SD 6 days). It is hypothesized that no routine gastric aspirate will decrease the number of days to reach 120 ml/kg/day by 3 days. One hundred and twenty six patients were required to have an 80% chance of detecting, as significant at the 5% level, a three day decrease in the number of days to reach 120 ml/kg/day of feeding in the no routine gastric aspirate group.

An independent researcher provided sequentially numbered, opaque and sealed allocation envelops using computer generated random numbers. The envelopes are kept in the NICU in a locked cabinet and it is the responsibility of the in-charge nurse in NICU to open the cabinet when a patients is identified to be included in the study and after obtaining an informed written consent from one of the parents.

Both groups will strictly follow the feeding protocol as per the unit protocol. Infants undergoing routine gastric aspiration will have pre-feeding aspiration every 6 hours. Infants in the no routine aspiration group will proceed with feeding with no aspiration and both groups will strictly follow a scheme in case of having vomiting, abdominal distension or other GI symptoms. The number of

days till reaching feed of 120cc/kg/day will be documented. All infants will be followed up until discharge.

Intervention Type
Procedure/Surgery

Primary outcome measure
The number of days until reaching feed of 120cc/kg/day

Secondary outcome measures
1. The number of days until reaching feed of 150 cc/kg/day
2. The number of days on parenteral nutrition (from admission until the time of reaching full feed)
3. The number of days until the removal of central lines (from the day of insertion upon admission or afterward before reaching full feed until removal)
4. The incidence of sepsis, defined as positive blood culture, throughout the hospital stay until discharge
5. The incidence of necrotizing enterocolitis, based on Bell staging stage 2 or more, throughout the hospital stay until discharge
6. Growth parameters: weight measured at 7, 14 and 21 days to get the average of weight gain gm/kg/day

Overall study start date
20/12/2015

Completion date
01/12/2019

Eligibility

Key inclusion criteria
Preterm infants equal or less than 32 weeks gestation

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
126

Total final enrolment
126

Key exclusion criteria

1. Any proved or suspected chromosomal abnormalities
2. Any gastrointestinal tract abnormalities
3. Patients with hypoxic ischemic insult

Date of first enrolment
11/04/2016

Date of final enrolment
11/05/2019

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Abdulaziz University Hospital
Jeddah
Saudi Arabia
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Sponsor information

Organisation
King Abdulaziz University

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Sponsor type
University/education

ROR
https://ror.org/02ma4wv74

Funder(s)

Funder type
University/education

Funder Name
King Abdulaziz University

Alternative Name(s)
, L'université du Roi Abdulaziz, La Universidad Rey Abdulaziz, King Abdulaziz University of Saudi Arabia, KAU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Saudi Arabia

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal.

Intention to publish date
01/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Hala Aljariry (haljariry@kau.edu.sa). The data will be available once the recruitment is completed. SPSS for Windows, version 21.0 (SPSS, Chicago, IL, USA) is used. A written consent was taken from the parents and a copy was kept with them, an additional copy in the patients file and a copy with the investigator. No ethical or legal restrictions.

IPD sharing plan summary
Available on request