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Biofilm (colonisation of microorganisms) formation in different types of nasogastric tubes used in preterm neonates

Submission date 04/03/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 11/11/2021	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 11/11/2021	**Condition category** Neonatal Diseases	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

Preterm babies in neonatal units require a number of procedures and equipment for their care including incubators, ventilators, monitoring devices, various tubes and catheters. Nasogastric (NG) tube insertion is one of the most common interventions undertaken in neonatal units. Depending upon the gestational age of the baby, the duration of NG tube placement is variable ranging from very short term (a few days) to long term (a few months).

Although the NG tube is needed and has been used for a long time in preterm babies in neonatal units, its effects on feed-related complications and microbiological associations are not thoroughly studied. The risk of infection is always taken seriously in the neonatal units and a number of strategies are put in place to prevent this. It is beyond doubt that immune-deficient preterm newborns in an intensive care setting are prone to colonisation (bacteria present and growing but not causing an infection) with a number of organisms, some of which can easily turn infective under favourable conditions for their growth.

In relation to the NG tubes, there is now enough evidence to suggest that microorganisms can grow in the form of a biofilm. The biofilm, in simpler terms, is a collection of organisms (bacteria, viruses and fungi) that can stick or grow on a variety of surfaces. Examples of biofilms include dental plaque and pond scum. A biofilm generally starts when free-floating bacteria come in contact with a suitable surface and can vary from very few layers of cells to a well-formed bacterial colony. It may potentially be a source of infection in preterm infants.

One of the most commonly used designs of NG tubes in neonates has a closed tip. There are new types of NG tubes that are now available which have an open tip and are being commonly used now. There have not been any controlled studies to suggest the advantage of one type of design over the other in the preterm population. The researchers' standard practice over the years had been to use the closed tip NG tube. The open-end tube has recently been introduced in clinical practice although not used very often.

The aim of this study is to analyse any differences in biofilm formation (bacterial colonisation) when different types of tubes are used. The researchers will also study its effects on certain feed-related complications, for example, intolerances, and the acidity of the stomach.

Who can participate?
Stable preterm infants born between 27+0 to 31+6 weeks gestation

What does the study involve?
As part of this study, infants are randomly allocated to one of two different types of NG tubes, one has a closed tip (current practice) and the other has an open tip (became available only recently). Both the tubes are safe to use. Having a plastic tube in any body cavity might promote the growth of bacteria and with this study, the researchers want to find out whether there are any differences in the way the bacteria grow depending upon which tube is used.

What are the possible benefits or risks of participating?
The researchers do see any risk of participating as the care received by the baby will not be affected. The perceived benefit is that biofilm formation might be reduced in the open tip design although the researchers do not know that as yet.

Where is the study run from?
The James Cook University Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2021 to December 2022

Who is funding the study?
The James Cook University Hospital (UK), also received funding from a commercial company (Avanos)

Who is the main contact?
Dr Shalabh Garg
s.garg@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Shalabh Garg

ORCID ID
https://orcid.org/0000-0001-5572-520X

Contact details
Consultant Neonatologist
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW
+44 (0)1642854834
s.garg@nhs.net

Additional identifiers

Integrated Research Application System (IRAS)
294415

Central Portfolio Management System (CPMS)
49886

Study information

Scientific Title
Randomised controlled trial to study the differences in the biofilm formation in occluded and open-tip nasogastric tubes in preterm neonates

Acronym
BOON

Study objectives
The insertion of nasogastric (NG) tubes in preterm neonates is one of the commonest procedures undertaken during their NICU stay. There are few observational studies to suggest that these NG tubes can get colonised with microorganisms (biofilm). Although the differences in the biofilm formation on the different type of NG tubes are not studied in preterm neonates. The two types of NG tubes available to be used in preterm babies are the open tip or the closed tip at the distal end.

It is hypothesized that there will be a significant reduction in the biofilm formation in the open tip design of the NG tube which will be studied in a randomised controlled trial in this study on preterm babies (27 to 31 weeks gestation)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Biofilm formation in preterm neonates

Interventions
Randomisation:
Minimisation using gestation (<30+0 weeks) yes/no. Twins and triplets will be allocated to the

same study arm. Secured, password-protected web-based randomisation using a minimisation algorithm (https://www.sealedenvelope.com or similar).

Interventions:
1. Commonly used closed-ended nasogastric tube (control group)
2. The newly available open-ended nasogastric tube (Intervention group)

Study duration:
7 days or less from the point of randomisation; some babies will be in the study for longer if the NG tube dislodged or had to be taken out due to clinical reasons before 4 days (presumed time period for possible biofilm formation based on the preliminary data).

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
1. Incidence of biofilm formation assessed by microbiological assay for each type of NG tube after it is removed
2. Colony forming units of the bacteria grown during microbiological culture for each type of NG tube after it is removed

Key secondary outcome(s)
1. Average gastric pH measured using [method] throughout the duration of NG tube in situ - between 4 to 7 days
2. The incidence of feed intolerance (nil by mouth, bilious aspirates, vomiting), measured using [method] for the duration of NG tube in situ - between 4 to 7 days

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Stable preterm infants born between 27+0 to 31+6 weeks gestation
2. Tolerating at least 48 ml/kg/day of enteral milk feed (chosen due to local preterm feeding protocol)
3. The clinical need for nasogastric tube insertion
4. Written informed consent from parents

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. No informed consent available
2. Not tolerating ≥50 ml/kg/day of enteral feeds
3. Known congenital anomaly or surgical condition of the GI tract

Date of first enrolment
01/06/2021

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The James Cook University Hospital
South Tees Hospitals NHS Foundation Trust
Neonatal Unit
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
James Cook Hospital

Funder Name
Avanos

Results and Publications

Individual participant data (IPD) sharing plan
In view of the Trust's governance guidance, the patient data will be kept confidential and only anonymous analysis can be shared. The data will be kept secure only on the hospital computers which are only to be used by authorised professionals.

IPD sharing plan summary
Not expected to be made available