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A post-market clinical study to evaluate the Kangaroo™ ePump enteral feeding pump automated water flushes on water delivery and compliance

Submission date
19/03/2014

Recruitment status
Stopped

Registration date
09/04/2014

Overall study status
Stopped

Last Edited
13/04/2015

Condition category
Other

[X] 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 feeding via a tube is a method used to feed patients who cannot attain an adequate oral intake from food and / or oral nutritional supplements, or who cannot eat or drink safely. The aim is to improve nutritional intake and so improve or maintain nutritional status. Enteral feeding can be delivered using a mechanical pump, which is the preferred method for patients requiring enteral feeding due to the ability to accurately control the rate of delivery of the feed. Mechanical occlusion (clogging) of the feeding tube is a frequent problem associated with enteral feeding. Clogging occurs for a variety of reasons. Consequences of feeding tube clogging include loss of nutrition, dehydration and missed medication due to inability to deliver feed, water or drugs. To prevent clogging of feeding tubes, it is routinely advised that tubes are flushed with water at certain specified time points.
The Covidien Kangaroo™ ePump is the first commercially available automated flush enteral feeding pump. This device is capable of delivering pre-programmed water flushes at regular intervals without any manual intervention once programmed. This study aims to evaluate this automated flushing capability and whether it reduces the burden on care staff to perform manual flushing, reduces feeding tube clogging and therefore reduces the time and cost associated with unclogging the tube as well as patient discomfort and/or adverse clinical outcomes associated with dehydration and inserting a new feeding tube. Participation in the study will not modify the standard treatment a patient receives. Participants will receive enteral feed and feeding tube flushes either via the Covidien Kangaroo™ ePump or a manual enteral feed pump with manual flushes as per current standard practice. The primary aim of this study is to evaluate the Kangaroo™ ePump programmable automated water flushes on water delivery and compliance as compared to the hospital standard manual flush pumps in patients requiring short term enteral feeding. Information will be collected on the volume of water and flushing frequency specified in the hospital protocol and initially prescribed by the clinician and the actual volume of water and frequency of flushing that the patient received in groups of patients using either the Kangaroo™ ePump Enteral Feeding Pump with automatic flush capability or the standard of care manual flush pump.

Who can participate?
Adult male and female patients 18 years of age and over prescribed enteral feeding for a minimum of 72 hours (3 days) will be considered candidates for this study.

What does the study involve?
For the study up to 110 subjects will be enrolled at two investigation sites in the United Kingdom over the course of 5 months. The minimum study duration for the patient will be approximately 3 days and the maximum will be 14 days. If all study inclusion and exclusion criteria are met, the participants will be randomly allocated to one of two groups: receive the KangarooTM ePump Enteral Feeding Pump or the hospital standard of care manual flush enteral feeding pump. Enteral feeding will commence utilising the randomly assigned feeding pump. Patient information will be collected during the course of pump use.

What are the possible benefits and risks of participating
There are no anticipated risks associated with participation in this study. However there may be complications associated with the insertion of the enteral feeding tube such as: risks associated with tube insertion or misplaced tube (may enter the lungs); pneumothorax, pneumonia, empyema, pulmonary haemorrhage, risks associated with hydration/dehydration/over hydrated. In addition to tube misplacement at the time of insertion, feeding tubes that were placed correctly can move out of the stomach at a later stage. This can be caused by coughing or vomiting. If misplacement of the feeding tube is not recognized before the infusion of the enteral feed commencement, this may result in a fatality.

Where is the study run from?
Up to 110 participants will be enrolled at two sites in the United Kingdom over the course of 5 months. The minimum study duration for the participant will be approximately 3 days and the maximum will be 14 days.

When is the study starting and how long is it expected to run for?
May 2014 to December 2014.

Who is funding the study?
This study is being funded by the manufacturer of the Kangaroo™ ePump, Covidien (USA).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
408.37

Study information

Scientific Title
A post-market, prospective, multi-center, open label, randomised clinical study to evaluate the Kangaroo™ ePump enteral feeding pump automated water flushes on water delivery and compliance

Study objectives
By delivering pre-programmed automatic flushes of water, the Covidien Kangaroo™ ePump has the ability to meet the prescribed water flushes automatically and reduce the occurrence of enteral feeding tube clogging which may positively impact patient hydration compared to a manual flush feed pump and manually administered flushes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West GM South REC, 13/03/2014, 14/NW/0120

Study design
Prospective multi-center open label randomised comparative study (AvB)

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Enteral feeding via a tube

Interventions
Patients are randomised to two groups. They will receive enteral feed and feeding tube flushes either via the Covidien Kangaroo™ ePump Enteral Feeding Pump or a manual enteral feed pump with manual flushes as per current standard hospital practice.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
To determine the difference of prescribed rates of water flushes to that of what was actually given and received by the patient. The difference among prescribed water volume and that which was received will be calculated for each group; the Kangaroo™ ePump and the standard of care, manual flush pump

1. The volume of water (used for flushing/hydrating) will be recorded in the bed side nursing charts on a daily basis and will be transcribed to the CRFs at Day 0, 1, 2, 3, 6, 10,and Day 14 or for the length of stay in hospital to a maximum of 14 days and
2. Flushing frequency (number of times/ rates flushed) will be recorded in the bed side nursing charts on a daily basis and will be transcribed to the CRFs at Day 0, 1, 2, 3, 6, 10,and Day 14 or for the length of stay in hospital to a maximum of 14 days.

Key secondary outcome(s))
1. The incidence of feeding tube occlusion
2. Interventions required to restore feeding tube patency
3. Time taken by health care staff in flushing enteral tubes, delivering additional water and tending to feeding tube occlusions to restore patency

Secondary measurements will be recorded in the bed side nursing charts on a daily basis and will be transcribed to the CRFs at Day 0, 1, 2, 3, 6, 10,and Day 14 or for the length of stay in hospital to a maximum of 14 days.

Completion date
01/12/2014

Reason abandoned (if study stopped)
Did not receive ethics approval

Eligibility

Key inclusion criteria
1. Male and Female patients ≥18 years of age
2. Be hospitalised in a monitored setting and about to commence enteral feeding per hospital standard of care using small bore nasogastric or nasojejunal feeding tubes for a minimum of 72 hours (3 days).
3. The subject or legally authorised representative is able to understand and willing to give written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients with a pre-existing feeding tube which will be used to deliver enteral feed during the course of the study
2. Incarcerated or imprisoned individuals
3. Patients who are currently enrolled in a competing clinical trial
4. Individuals, who, in the opinion of the Principal Investigator, have any medical, social, or psychological condition that would compromise their participation in this clinical study
5. Patients requiring enteral feed for less than 72 hours

Date of first enrolment
01/05/2014

Date of final enrolment
01/12/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southampton General Hospital
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Covidien (USA)

ROR
https://ror.org/00grd1h17

Funder(s)

Funder type

Industry

Funder Name
Covidien (USA)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No