

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/04/2014	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/04/2015	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 Kangaroo™ 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?

Trevor Smith
trevorsmith@nhs.net

Contact information

Type(s)

Scientific

Contact name

Dr Trevor Smith

Contact details

Southampton General Hospital
Tremona Road
Southampton
United Kingdom

SO16 6YD

-

trevorsmith@nhs.net

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

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

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/05/2014

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

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**

England

United Kingdom

Study participating centre

Southampton General Hospital
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation

Covidien (USA)

Sponsor details

15 Hampshire Street

Mansfield

United States of America

02048

-

shay.caravaggio@covidien.com

Sponsor type

Industry

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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