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Pre-treatment gastrostomy tube versus oral feeding plus as-needed nasogastric tube feeding in patients undergoing chemoradiation for head and neck cancer

Submission date
12/06/2014

Recruitment status
No longer recruiting

Registration date
12/06/2014

Overall study status
Completed

Last Edited
28/04/2020

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/trials/A-trial-looking-two-different-ways-feeding-during-treatment-head-and-neck-cancer-tube

Study website
Under development

Contact information

Type(s)
Scientific

Contact name
Miss Ann Marie Hynes

Contact details
Clinical Trials Unit
Faculty of Medical Sciences
Newcastle University
1 – 4 Claremont Terrace
Newcastle upon Tyne
United Kingdom
NE2 4AE
+44 (0)191 208 7647
Ann.hynes@newcastle.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16822

Study information

Scientific Title
A feasibility randomised controlled trial of pre-treatment gastrostomy tube versus oral feeding plus as-needed nasogastric tube feeding in patients undergoing chemoradiation for head and neck cancer

Acronym
TUBE

Study objectives
A multicentre randomised controlled feasibility trial comparing oral feeding plus pre-treatment gastrostomy versus oral plus as-required nasogastric tube feeding in patients with head and neck squamous cell cancer (HNSCC).

The principal aim is to determine whether a definitive RCT in head and neck cancer patients undergoing chemoradiation comparing oral feeding plus prophylactic gastrostomy tube feeding versus oral feeding plus as-needed nasogastric tube feeding is feasible. Second, we seek further clarity as to how a definitive trial should best be designed from the perspectives of patients, clinicians and NHS resources. The TUBE study feasibility trial is a necessary prelude to a full trial of these complex interventions, to assess whether an adequate proportion of eligible patients can be recruited and retained in the study as assessed, both quantitatively and qualitatively.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/123532
Protocol can be found at: https://njl-admin.nihr.ac.uk/document/download/2007246

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/NE/0045; First MREC approval date 26/02/2014

Study design
Randomised; Interventional; Design type: Process of Care, Treatment

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
Topic: Cancer, Ear, nose and throat, Gastroenterology; Subtopic: Head and Neck Cancer, Ear (all Subtopics), Gastroenterology; Disease: Head and Neck, Ear, nose & throat, All Gastroenterology

Interventions
Study participants will be randomised to one of two treatment arms in a 1:1 ratio:

1. Pre-CRT (chemo-radiation treatment) gastrostomy arm
G-tube insertion will take place before CRT commences, ideally in weeks two and three after most patients are randomised. Where patients are receiving induction chemotherapy G-tube (gastrostomy tube) insertion may take place on either the week before cycle 2 of induction or the week pre CRT. G-tubes are inserted into the stomach through an abdominal incision, by either endoscopic or radiologic guidance, both being functionally equivalent. The choice of method of insertion will be left to the treating clinician/centre. Patients will continue with oral feeding throughout CRT unless or until they are unable to maintain an adequate oral intake to meet their nutritional requirements or are unable to swallow. At this stage the use of liquid nutrition through the G-tube will commence.

2. No pre-CRT gastrostomy arm
This group of patients will continue oral feeding throughout CRT, unless or until they are unable to maintain an adequate oral intake or inability to swallow, when a naso-gastric (NG) tube will be placed under local anaesthesia and liquid nutrition via an NGT will commence. The decision to place a nasogastric tube will be based on clinical assessment, patient request and published guidelines.

In both arms, patients will be given information about the treatment and the intervention involved. This will be delivered by the PI at the centre and reinforced by the research nurse.

Follow-up will occur weekly during CRT (for up to 8 weeks) and then a post CRT follow-up will be performed, as well as follow-up at 3, 6 and 12 months. These will all coincide with routine clinical appointments

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Assess willingness to randomise (by qualitative interviews with clinicians) and be randomised (by review of patient screening logs)
2. Assess retention and drop-out rates

Secondary outcome measures

1. Assess compliance and refine interventions and study processes
2. Estimate parameters to inform definitive trial design
3. Assess value of information based on modelling exercise
4. Assess incidence of reported adverse events

Overall study start date
14/06/2014

Completion date
14/06/2016

Eligibility

Key inclusion criteria
Patients with stage III and IV HNSCC who are suitable for primary CRT with curative intent. This can include patients having induction chemotherapy prior to CRT. All patients would have been investigated and diagnosed as above by the respective cancer MDT.
Main inclusion criteria are as follows:
1. Grade 1 pre-treatment dysphagia, as defined by Common Terminology Criteria for Adverse Events v4.0 (defined as: asymptomatic/symptomatic/able to eat regular diet)
2. Consent to be randomised
3. Adult patients

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
Patients who:
1. Decline to participate
2. Are unable to give informed consent
3. Cannot receive a gastrostomy for medical reasons
4. Do not receive treatment with curative intent
5. Have malnutrition requiring immediate initiation of enteral feeding

Date of first enrolment
10/07/2014

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
United Kingdom

Study participating centre
Please contact the Trial Manager for more information on individual participating sites
United Kingdom
-

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Joint Research Office
Level 6, Leazes Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Our exact publication policy is not yet known although conference presentations and a peer-reviewed journal article/s are highly likely. We also plan to publish our study protocol.
We do not plan to inform patients of results on an individual basis; however, we will aim to disseminate findings to the public (and hence patients) through a range of mechanisms including:
1. Local patient representatives who have been involved with the project from inception will help disseminate the findings to local patient networks.
2. The applicants' links with the head and neck studies group of the NCRI and its patient representative will help disseminate findings through national support groups.
3. We aim to plan a dysphagia workshop timed to coincide with the final stages of the study. We intend to invite patients to this workshop, to disseminate study results among patient groups.
4. We have booked the domain name www.tubestudy.co.uk, and propose to use the TUBE website as a means of publicising the trial progress and results.
5. The results will also be publicised in national media, with the aid of press releases from the Newcastle upon Tyne Hospitals Foundation Trust and Newcastle University.

Intention to publish date
14/02/2018

Individual participant data (IPD) sharing plan
All available data will be included as an appendix to the report to be published on 14/02/2018.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	16/06/2016		Yes	No
Results article	results	01/04/2018		Yes	No
Plain English results			28/04/2020	No	Yes
HRA research summary			28/06/2023	No	No