ISRCTN57646445 https://doi.org/10.1186/ISRCTN57646445

The effect of comprehensive intervention with the clinical pathway for eating and swallowing disorder in the elderly with dementia

Submission date
02/12/2015

Recruitment status
No longer recruiting

Registration date
08/12/2015

Overall study status
Completed

Last Edited
26/09/2017

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
The natural clinical course of advanced dementia has been reported in a few studies. They often experience problems with eating and drinking, but the reason for this has not been clarified. The causes for any individual patient can be unclear, because most of those patients are nearing the end-of-life and are not likely to be assessed adequately. However, the prognosis of these patients can be improved by giving them treatments (or interventions) that help them to be able to eat. In Japan, it is recommended that elderly patients have a comprehensive geriatric assessment (CGA). This has been shown to improve their functional status (that is, improve their ability to perform normal daily activities) and prognosis for some diseases (for example, chronic heart failure and pneumonia). This study investigates whether an intervention based on CGA can also help patients suffering from eating and swallowing disorder of the elderly with dementia (ESDED).A special ESDED team has been set up called the "Eating and Swallowing Assessment Team (ESAT)" which consists of medical doctors, dentists, dental hygienists, pharmacists, nurses, speech therapists, physical therapists, occupational therapists, dieticians and certified care workers. This team has developed a new system to examine ESDEDs using the original clinical pathway (CP). This CP involves assessments by each specialist and integration of their findings followed by diagnosing the etiology (cause) of ESDED in each patient. Based on the diagnosis, ESAT designs various interventional methods (treatments) and passes this information to the medical staff treating the ESDED. This study looks at whether this medical care system based on CGA improves the ability of eating and prognosis of the patients with ESDEDs.

Who can participate?
Elderly patients aged over 70 with cognitive impairment (difficulties in thinking and memory), who need to be treated with artificial hydration and/or nutrition.

What does the study involve?
Each participant has a CGA developed by the ESAT. For the first two days this involves assessing the patients various functions (physical, cognitive, chewing, swallowing, and sensory), collecting their past medical and medication history, and obtaining detailed information of their eating problems. The team perform a physical and dental examination, urine and blood examination,

chest X-ray, electrocardiogram, and magnetic resonance imaging of the brain of each patient. In addition, the behavior and reaction of each patient during nursing at dinner is observed and a list of the problems that they are having swallowing is drawn up. On the third day, a video-endoscopic examination of the patients swallowing is done, after which the ESAT decides the cause of the problems each patient has with eating. This is based on all the data that has been collected. The ESAT then plans further assessment or examination in order to identify the details of the etiology for each patient. On days 4 and 5, the ESAT perform the planned assessment or examinations and makes the final diagnosis for the etiology of the eating problem experienced by each patient. Based on the diagnosis, ESAT proposes various interventional strategies to the medical staff who treat the ESDED.

What are the possible benefits and risks of participating?
The participants might be able to be withdrawn from AHN. However, they might have a risk of receiving an excessive assessment or intervention, which would be unnecessary for their original medical care.

Where is the study run from?
Nanto Municipal Hospital (Japan)

When is the study starting and how long is it expected to run for?
April 2012 to June 2016

Who is funding the study?
Japan Primary Care Association

Who is the main contact?
Dr Masahisa Arahata

Contact information

Type(s)
Scientific

Contact name
Dr Masahisa Arahata

ORCID ID
http://orcid.org/0000-0002-3759-0724

Contact details
Nanto Municipal Hospital
938 Inami
Nanto
Japan
939-0211

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of comprehensive assessment with multi-disciplinary interventions for eating and swallowing disorders in the elderly with dementia; non-randomized, historical controlled, interventional study

Study objectives
The comprehensive assessment with multi-disciplinary interventions could determine the details of etiologies of eating and swallowing disorders in the elderly patients with dementia, which would help the improvement of the functional status of the eating leading to better overall survival of those patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Review Board of Nanto Municipal Hospital, 21/03/2013, ref: # 664

Study design
Non-randomized historical-controlled interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Eating and swallowing disorder of the elderly with dementia (ESDED)

Interventions

The subjects receive comprehensive geriatric assessment (CGA) through the original clinical pathway with multi-disciplinary interventions followed by the individualized therapeutic interventions according to the assessment of the etiology of their eating problems.

Intervention Type
Mixed

Primary outcome measure
1. Recovery rate (RR): RR represents the rate of participants who become free from AHN by taking enough amounts of nutrition and water orally for at least 7 days (longer than 7 days). If they cannot be withdrawn from AHN before discharge from the hospital, they are considered to be failed
2. AHN free survival (AHNFS): AHFNS represents the survival rate of participants who have become free from AHN. AHFNS is assessed by Kaplan Meier method, in which each participant is estimated to reach the endpoint if the participant is dead or becomes dependent on AHN. The survival rate is measured one year after withdrawal from AHN

Secondary outcome measures
The overall survival (OS) after onset of ESDED: OS is assessed by Kaplan Meier method, in which each participant's endpoint is death. The survival rate is measured one year after the onset of ESDED

Overall study start date
01/04/2012

Completion date
30/06/2016

Eligibility

Key inclusion criteria
Participants were required to meet all the following five criteria, all of which are the characteristics of ESDED:
1. A hospitalized patient aged over 70
2. Cognitive impairment (Mini-Mental-State-Examination <24, or Hasegawa-Dementia-rating-Scale-Revised <21)
3. A patient who did not receive intravenous or surgical treatment for past 7 days
4. Oral intake is no more than 500 kilo-calories per day
5. Dependent on AHN for over 7 days

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
120

Key exclusion criteria
Potential participants are excluded from this trial if they meet any of the following criteria:
1. A patient who has determined to depend on persistent tube-feeding
2. A patient with morphological anomaly due to a tracheotomy or an operation to remove all or a part of the larynx
3. A patient who has been receiving an end-of-life care

Date of first enrolment
01/04/2013

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
Japan

Study participating centre
Nanto Municipal Hospital
938 Inami
Nanto
Japan
932-0211

Sponsor information

Organisation
Nanto Municipal Hospital

Sponsor details
938 Inami
Nanto
Japan
932-0211

Sponsor type
Hospital/treatment centre

Website
http://shiminhp.city.nanto.toyama.jp/

Funder(s)

Funder type
Government

Funder Name
Japan Primary Care Association

Results and Publications

Publication and dissemination plan
The trialists will collect all the data of outcomes until July 2016. Therefore, they will write and submit the article on this study in August or September 2016.

Intention to publish date
30/09/2016

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 Masahisa Arahata. The dataset including both intervention group and historical group can be obtained from today, and this will be stored as long as possible (at least 5 years from publication). The dataset consists of personal data (patient no., allocated group, age, sex, baseline characteristics, outcomes, other clinical data, and so on) stored in a Microsoft Excel file suitable for EZR. All personal data was completely anonymized. EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan) is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria), which is used for statistical analysis in many studies. In order to obtain the dataset of the trial and use for other studies, another ethics approval (from the trialists' institution and/or about the new study) will be necessary. A fee may be required for preparation of a new ethics approval.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/07/2017		Yes	No