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Chlorhexidine or toothpaste, manual or powered brushing to prevent pneumonia complicating stroke (CHOSEN feasibility trial)

Submission date
02/02/2021

Recruitment status
No longer recruiting

Registration date
17/02/2021

Overall study status
Completed

Last Edited
10/10/2024

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
We want to find out whether cleaning the mouth after a stroke could reduce the likelihood of getting infections in the lung (pneumonia). Before we can test this in a large clinical trial, we need to conduct a smaller trial to check if our plans are achievable. 100,000 people in the UK have a stroke each year. After a stroke it can be difficult for people to swallow or to keep their teeth and mouth clean. Together, these problems can lead to harmful bacteria building up in the mouth and causing pneumonia. As many people with stroke and swallowing problems suffer from pneumonia we want to know how best to keep their mouths clean when they are in hospital. At this stage, we don't know which approach is best to prevent pneumonia, or even which approach is most suitable for people with stroke.
If this trial is positive, it will provide important information for a larger trial to see whether mouth care treatments can actually reduce the chances of pneumonia developing after stroke

Who can participate?
Stroke patients aged 18 years or above, with swallowing problems.

What does the study involve?
We will undertake a trial in stroke units at four hospitals. Nurses on the stroke units will receive training in how to deliver our mouth care intervention. 120 stroke patients with swallowing problems will be consented within 24 hours of coming into hospital and divided randomly into one of 4 groups
1. Toothpaste and manual toothbrush
2. Toothpaste and powered toothbrush
3. Antiseptic gel and manual toothbrush
4. Antiseptic gel and powered toothbrush
We will assess whether these mouth care treatments are feasible by looking at how many stroke patients agree to participate, how often they receive the treatment and how many complete the trial. We will see whether the treatments are acceptable by gathering the views of patients, their carers and the nursing staff. We will also collect information about how often pneumonia develops, how long participants stay in hospital, their quality of life and how well they recover.

What are the possible benefits and risks of participating?
This is a feasibility trial and cannot promise benefit. All participants will receive twice-daily oral healthcare which may improve comfort and well-being. There are no major risks associated with trial participation; as all staff will have completed training on delivering the allocated oral health care OHC interventions prior to the start of recruitment. Some participants may find the OHC intervention uncomfortable. Staff will offer regular short breaks and will stop completely if the OHC intervention becomes too uncomfortable. There is a potential risk of allergy to chlorhexidine toothpaste and potential risk of staining of the teeth. Should either occur, the participant would discontinue the allocated OHC intervention and be offered the option to change to standard non-foaming toothpaste or withdraw from the trial.

Where is the study run from?
Salford Royal NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2020 to August 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Craig J. Smith, craig.smith-2@manchester.ac.uk

Study website
https://sites.manchester.ac.uk/chosen/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
270544

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
CPMS 48055, IRAS 270544

Study information

Scientific Title
CHlorhexidine Or toothpaSte, manual or powered brushing to prEvent pNeumonia complicating stroke (CHOSEN): a 2x2 factorial randomised controlled feasibility trial

Acronym
CHOSEN

Study objectives
We want to find out whether cleaning the mouth after a stroke could reduce the likelihood of getting infections in the lung (pneumonia).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/03/2021, Leeds Bradford REC (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8109; bradfordleeds.rec@hra.nhs.uk), ref: 21/YH/0014

Study design
Interventional randomized controlled trial with qualitative follow up

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Tooth brushing to prevent pneumonia complicating stroke

Interventions
Following consent/declaration, the CRN practitioner will conduct Visit 1 - Baseline assessment. Once complete, the participant will be randomised to the Oral Healthcare (OHC) intervention arm - either:
1. Chlorhexidine 1% gel toothpaste with a manual toothbrush
2. Chlorhexidine 1% gel toothpaste with a powered toothbrush
3. Non-foaming toothpaste with a manual toothbrush
4. Non-foaming toothpaste with a powered toothbrush

A total of 120 patients will be randomised and the randomisation system will ensure equal number of participants in each OHC intervention arm at each recruiting site.

Intervention:
The allocated OHC treatment will be prescribed on the clinical prescription card by a delegated member of the research team (including non-medical prescribers as deemed appropriate by local Principal Investigator). This will facilitate evaluation of fidelity and/or tolerability by allowing staff to document receipt or reason for non-receipt.

The OHC intervention will be delivered twice-daily for two minutes on each occasion by members of the ward nursing team (nurses and healthcare assistants) who have completed the education and training programme. The patient will be sat in an upright position and bedside suction will be available if required. Patients will dentures will receive the allocated OHC intervention and standardised denture care. The OHC intervention will be given until discharge from inpatient stroke services or until 3 months (whichever is sooner). The patient will be given the toothbrush to take home if requested but no further supplies of the allocated OHC equipment will be provided after discharge.

Trial visits (note: not all visits are performed face-to-face):
Visit 1 (Baseline assessment) - Performed following consent and before randomisation. CRN practitioners will conduct a face-to-face baseline assessment with the patient. This will record details such as age, sex, details of stroke, risk factors, medications, level of disability in the month prior to stroke (using National Institutes for Health Stroke Scale; NIHSS) and interval from admission to randomisation. This visit will also include a dental examination. The CRN practitioner will use validated assessment tools to assess the condition of the mouth e.g. The Holistic Oral Assessment Tool (THROAT score) and General Oral Health Assessment Index (GOHAI). As part of this mouth assessment, the CRN practitioner will record data on number of natural teeth, denture status, nutritional status (e.g. nil by mouth, receiving modified or normal diet or nutrition delivered via a naso-gastric tube or into a vein).

Visit 2 - Face-to-face visit performed by CRN practitioners on one occasion between 7-10 days post-randomisation - The CRN practitioner will repeat the THROAT score and GOHAI and collect data on swallow and nutritional status, details of treatment fidelity (number of OHC interventions received and reasons for non-delivery), adverse/serious adverse events (including specific data on incident pneumonia i.e. antibiotic initiation/number of doses and diagnosis).

Visit 3 - Data will be collected weekly starting 14 days from date of randomisation until discharge or 3 months post-randomisation. The data will be collected from information recorded in the medical record/electronic patient record as this is not a face-to-face visit. Data collected on each occasion will be identified as 'visit' 3a, 3b, 3c etc) - CRN practitioners will record swallow and nutrition status, treatment fidelity data, incident pneumonia and adverse events.

Visit 4 Discharge/withdrawal visit - This is a face-to-face visit (unless withdrawn) and may be performed up to 24h before discharge or up to 24h after withdrawal. The CRN practitioner will record treatment fidelity, repeat the assessment tools e.g. GOHAI, quality of life score (EQ-5D-5L), modified Rankin Scale (level of disability) and record data on length of hospital stage, discharge destination, incident pneumonia (including number of antibiotic doses) and adverse /serious adverse events.

Visit 5 - Final assessment performed by telephone at 3 months from date of randomisation (+/- 7 days) - This will be performed by CRN practitioners by telephone with the participant and/or the personal consultee (if participant has still not recovered capacity) and will record survival, modified Rankin Scale score and information about post-discharge mouth care. If the participant has not been discharged home by 3 months, Visits 4 (discharge) and Visit 5 (outcome assessment) will be performed as a single face-to-face visit at 3m post stroke onset (Visit 4A). This will complete trial participation.

Development of the Implementation Package
To maximise the pathway to impact and to ensure fidelity, we will develop an implementation strategy prior to commencing recruitment of stroke patient participants into the feasibility trial. This will involve undertaking focus groups at each site underpinned by the Theoretical Domains Framework (TDF) to identify barriers and facilitators to implementation of the OHC interventions. These will then be presented to an implementation group, who will develop the implementation strategy.

Focus groups
The focus groups (1-2 per site) up to a total of 16 people, who will be a mixture of stroke unit staff, stroke survivors and relatives/carers of stroke survivors.
To provide a wide range of perspectives with regard to the OHC interventions and their potential acceptability, it is of paramount importance that the development of this implementation strategy includes input from a wide range of patients, relatives/carers and staff. In order to achieve this broad representation purposive sampling will be used. If the COVID-19 pandemic is still an issue at this time, the focus groups will ensure all social distancing rules are applied, the venue size is appropriate and the personal-protective equipment is worn by researchers and made available to participants. If any participants feels uncomfortable to attend in person, provision may be made to conduct the focus group using appropriate video conferencing platform.

The focus groups will be undertaken with a facilitator and a note taker. Questions within the topic guide will be posed, probes and follow up questions will be used to explore the key concepts more deeply. For participants with communication difficulties, they will be supported to participate by a SLT using a number of adapted communication methods which will be tailored to individual patient needs, for example, pictorial representations of activities, or visual analogue scales to express degrees of agreement.

When group members are unable to attend focus group meetings, individual interviews may be offered as an alternative, conducted by a member of the UCLan research team.

Process Evaluation
We will undertake a parallel theoretically informed process evaluation, which will focus on understanding fidelity to the OHC treatments and patient outcomes.

Evaluating fidelity to the OHC interventions
The allocated OHC intervention will be prescribed on the participant's drug chart, on which staff will record whether the patient received the intervention. Reasons for non-receipt will be made when the format of the drug chart allows. Review of the drug charts will be made every two weeks during the first two months of the intervention period in order to evaluate fidelity to the allocated OHC intervention for each patient. If the intervention is not being implemented as per protocol, the need for further training will be reviewed

Post-implementation questionnaires
All staff will be invited to complete a post-implementation questionnaire to explore staff experiences in implementing the OHC intervention, identifying their perceived barriers and facilitators to fidelity and embedding the intervention into routine clinical practice. This questionnaire will provide a wide range of responses across the sites.

Interviews - Staff
Further to the post-implementation questionnaire, semi-structured interviews will further explore the experiences of implementing the intervention and the issues related to embedding the OHC interventions into routine practice. They will be underpinned by the TDF, capturing data surrounding perceived adequacy of and ability to retain training and knowledge, beliefs about capabilities, consequences and patient expectations, acceptability and tolerability of the OHC interventions, environmental context and resources, and professional roles and identity. The interviews will establish what staff thought worked well about the intervention as well as identifying areas for improvement, thereby providing ideas for refinement of trial procedures and protocol should a larger scale trial be conducted in future.
Interviews will be undertaken with a sub-set of clinical staff (n=4-6 per site) who completed the post-implementation questionnaire, selected using maximum variance techniques, selected based on their clinical role and grade, and their experience of implementing the OHC intervention.
Interviews will be carried out on site or via telephone depending on individual preference.

Interviews - Patients and Relatives
Semi-structured interviews will be undertaken with a sub-set of patients and carers/relatives, exploring their experience of the OHC intervention including acceptability factors which may have impacted on their adherence to the intervention.

A sample of patients and carers/relatives (approximately n=4-6 per site) will be purposively selected for a semistructured interview. This selection will be made using maximum variance techniques to generate a range of potential participants with regard to gender, age, stroke severity and whether they adhered to the OHC intervention.

All interviews with participants with impaired communication will be conducted by a member of the UCLan research team who is a qualified Speech and Language Therapist with extensive experience working with stroke survivors and their carers/relatives. This researcher will use a number of supported conversation techniques which will be tailored to the individual needs of each participant with impaired communication. These may include adjusting the speed, length and complexity of the questions being asked, using pictures and/or written words to support a participant's understanding, providing means for participants to use writing and/or pictures to express themselves, use of visual analogue scales to express degrees of emotions.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Manual or powered toothbrush, with 1% chlorhexidine toothpaste or non-foaming toothpaste

Primary outcome measure
Feasibility outcome:
Recruitment and set-up of sites within 6 months of study start measured as confirmation of Capacity & Capability (C&C) from each site

Secondary outcome measures
1. Implementation of staff education and training at all four participating sites within 3 months of trial start date measured using Theoretical Domains Framework (TDF) to identify barriers and facilitators to implementation of the OHC interventions.
2. Recruitment of participants to work stream 1 (feasibility) within 15 months of trial start date measured as monthly recruitment of 8 participants
3. Retention of consented participants measured as those receiving allocated oral healthcare (OHC) intervention until discharge/repatriation from participating site for a maximum of 3 months from date of stroke symptom-onset and by completion of follow-up (by telephone or face-toface) at 3 months from date of stroke symptom-onset
4. Adherence to allocated OHC treatment measured as those receiving allocated OHC intervention twice-daily until discharge/repatriation from participating site for a maximum of 3 months from date of stroke symptom-onset
5. Measured weekly from 14 days from stroke-onset to maximum 3 months and discharge:
5.1. Swallow status will be measured weekly from 14 days from stroke-onset to maximum 3 months and discharge by capturing the result of any clinical Speech & Language Therapy (SLT) or bedside swallow assessment
5.2. Incident pneumonia based on CDC criteria
5.3. Oral health measured using the Geriatric Oral Health Assessment Index (GOHAI)
6. Condition of the oral cavity will be measured using THROAT score at 7-10 days from stroke-onset
7. Adverse events measured using patient records at 7-10 days from stroke-onset
8. Disability measured using the modified Rankin Scale score at 3 months from stroke-onset

Overall study start date
01/09/2021

Completion date
30/08/2023

Eligibility

Key inclusion criteria
Main study
1. Aged 18 years or over
2. Within 24 hours of admission with acute ischaemic or haemorrhage stroke

3. Dysphagic* (failed bedside swallow or Speech & Language Therapy Assessment at any stage during admission when screened for inclusion, even if now resolved at time of screening)
4. At least one natural tooth
5. Informed consent available from participant and/or personal or professional consultee

Focus group - Patients
1. Aged 18 years or over
2. Able to successfully engage in conversation by any means (receptive and/or expressive communication impairment with supported conversation techniques when required)
3. Dysphagic (failed bedside swallow or Speech & Language Therapy Assessment) at any stage during their stay
4. At least one natural tooth
5. Informed consent available from participant and/or personal or professional consultee

Focus group -Relatives/Carers of Stroke Survivors
1. Aged 18 years or over
2. Carers or relatives of stroke survivors currently being cared for or previously cared for (last 3 months) on the stroke unit at one of the four hospital sites, who have been dysphagic at any time during their stay

Focus group - staff
1. A member of clinical staff working on the stroke unit at one of the four hospital sites

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 232; UK Sample Size: 232

Total final enrolment
218

Key exclusion criteria
Main study
1. Planned repatriation to non-participating site
2. Planned imminent mechanical ventilation or palliative care
3. No natural teeth
4. Known allergy to chlorhexidine
5. Confirmed SARS-Cov-2 infection at time of screening
6. Receiving antibiotic therapy for chest infection at time of screening
7. Clinically significant serious concurrent medical condition, pre morbid illnesses, or concurrent serious infection, at the PI's (or designee's) discretion, which could affect the safety or

tolerability of the intervention
8. Patients currently participating in other Clinical Trial of an Investigational Medicinal Product (CTIMP) may be co-enrolled at the discretion of the PI of the relevant CTIMP

Focus groups
No specific exclusion criteria

Date of first enrolment
01/10/2021

Date of final enrolment
30/04/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salford Royal Hospital
Salford Royal NHS Foundation Trust
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Fairfield Hospital
Rochdale Old Rd
Bury
United Kingdom
BL9 7TD

Study participating centre
Whiston Hospital
St Helens and Knowsley Teaching Hospitals NHS Trust
Warrington Road
Prescot
United Kingdom
L35 5DR

Study participating centre
Royal Preston Hospital
Lancashire Teaching Hospitals NHS Foundation Trust
Sharoe Green Lane North
Fulwood
Preston
United Kingdom
PR2 9HT

Sponsor information

Organisation
Salford Royal NHS Foundation Trust

Sponsor details
Summerfield House
Eccles New Road
Salford
England
United Kingdom
M5 5AP
+44 (0)161 2065235
steve.woby@srft.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.srft.nhs.uk/

ROR
https://ror.org/019j78370

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR200739

Funder Name

National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal, at national conference and via the trial website.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
Once the results of the study have been published, the CHOSEN website will be updated with the results and the individual participants can access the information there.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

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