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Feasibility study of the treatment of oral mucositis from radiotherapy

Submission date
18/10/2025

Recruitment status
Recruiting

Registration date
22/10/2025

Overall study status
Ongoing

Last Edited
22/10/2025

Condition category
Cancer

[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
Oral mucositis (OM) is damage to the lining of the mouth and throat caused by cancer treatment, including radiotherapy, chemotherapy and more recently proton beam therapy. It is a very common adverse effect which is long-lasting and causes severe side effects, including pain, secondary infection, affects eating and drinking and causes weight loss, reduces quality of life, increases healthcare use, and costs of painkillers and placement of feeding tubes. Current treatments are based on limited evidence, are not all widely available or require specialised equipment, and there is an urgent need for research into other safe, effective treatments. The limited research which has been conducted on the herbal extract being investigated suggests that it is safe and possibly beneficial, has all been conducted in countries outside Europe, and none in the UK or with products available in the UK. Further research is required to confirm its safety and effectiveness. The proposed study is a small 'feasibility trial' to evaluate all aspects of the research process and inform the design of a larger study investigating the effect of a herbal extract on oral mucositis in head and neck cancer participants undergoing radiotherapy.

Who can participate?
Adult patients undergoing radiotherapy for head and neck cancer.

What does the study involve?
If a participant decides to take part in the study, a computer will randomly assign them, similar to flipping a coin, to either receive information about the study treatment or to receive usual care if they develop oral mucositis (OM) symptoms, as previously described. The study treatment being investigated is a commonly used herbal extract.

Regardless of group allocation, participants will be asked to complete four questionnaires on three separate occasions. Each set of questionnaires will take approximately 25 minutes to complete and will assess cancer symptoms and quality of life. These questionnaires will be administered at the start of treatment, weekly during treatment, and again at 1, 2, and 3 months post-treatment. Participants will also be asked to provide demographic information, including age, education, and socioeconomic characteristics, although they may choose not to answer these questions.

All participants, regardless of treatment group, will be invited to take part in a telephone interview once treatment has commenced. The interview will explore participants' views on the study, and for those allocated to the turmeric supplement group, their experiences of taking it. Interviews will last approximately 45 minutes and can be scheduled at a time and location convenient for the participant.

Participants assigned to receive information about the study treatment will be provided with a separate consent form and may decide later whether they wish to participate in the treatment component of the study.

What are the possible benefits and risks of participating?
Participation in the study carries the risk that the study approach may not be as effective as the usual care. There is also a possibility of experiencing side effects from the turmeric supplement, which may differ from or be more severe than those associated with standard OM treatment.

The herbal extract is generally considered safe, and serious side effects are rare. However, minor side effects may occur, including gastrointestinal symptoms (nausea, constipation, diarrhoea, increased stool frequency), headache, sleepiness, high blood pressure, abdominal bloating, feeling cold, bruising, fever, foot swelling, throat infection, itching, dizziness, and hot flushes. The extract may also affect blood thickness and interact with certain medications, which will be reviewed during the eligibility assessment.

Where is the study run from?
The study is run from University College Hospital, London, with other sites at Guy's and St Thomas' Hospital, London, and the Christie Hospital, Manchester, UK.

When is the study starting and how long is it expected to run for?
The study is planned to start in early 2026 and recruitment is likely to last for at least 6 months.

Who is funding the study?
The University College London Hospitals Charitable Trust, UK.

Who is the main contact?
Dr Saul Berkovitz (Chief Investigator), uclh.rlhim.donotreplyadmin@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
361112

Protocol serial number
Nil known

Study information

Scientific Title
A feasibility study of treatment of oral mucositis due to radiotherapy in cancer of the head and neck (TOMRIC)

Acronym
TOMRIC

Study objectives
This feasibility trial will evaluate all aspects of the research process and inform the design of a fully-powered, pragmatic randomised controlled multi-centre clinical trial investigating the effect of a herbal extract on oral mucositis in head and neck cancer participants undergoing radiotherapy.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/06/2025, School of Medicine and Biosciences School Research Ethics Panel (SCREP) (School of Medicine & Biosciences, University of West London, Ealing, London, W5 5RF, United Kingdom; +44 (0)800 0368888; Michael.Loughlin@uwl.ac.uk), ref: UWL/REC/SBS-01190

Study design
Randomized controlled feasibility study

Primary study design
Interventional

Study type(s)
Prevention, Treatment

Health condition(s) or problem(s) studied
Prevention of oral mucositis in patients with head and neck cancer undergoing radiotherapy

Interventions
The study will employ a pragmatic mixed-methods randomised parallel-group exploratory design to determine the feasibility of giving a herbal extract within an NHS cancer care setting. The

study will compare the herbal extract plus standard care versus standard care alone. Participants will be allocated to treatment arms by computer-generated randomisation. Participants will complete baseline outcome measures and be asked to complete follow-up outcome measures weekly during radiotherapy and one month post-radiotherapy treatment. At two months post-radiotherapy treatment, all participants will be invited to participate in a qualitative interview to explore their views on the design of the trial, and for those allocated to the herbal arm, their views on the intervention. Participants will be randomised using a ratio of 1:2 standard care to herbal extract. Participants in the standard care arm will be offered the herbal extract at the end of the trial to deal with any ongoing oral mucositis.

Intervention Type
Supplement

Primary outcome(s)
The primary aim of this study is to establish the feasibility of a future definitive trial; as such, its primary outcome measures evaluate:
1. Recruitment processes and resources
1.1. Eligibility: The number of patients with cancer eligible for recruitment will be assessed through site referral counts, on-site researcher monitoring, and stakeholder qualitative interviews at recruitment.
1.2. Recruitment (Participation): The ability to recruit patients into the study will be measured by the number of patients consenting, on-site researcher monitoring, and qualitative interviews with stakeholders and patients during recruitment.
1.3. Recruitment (Decliners): The number of patients declining to participate and their reasons will be evaluated through site monitoring and qualitative interviews with stakeholders and patients at recruitment.
1.4. Randomisation: Willingness to be randomised will be explored through patient qualitative interviews at the point of randomisation.
1.5. Retention: Retention across the duration of the intervention will be measured using quantitative dropout data and qualitative interviews with patients and stakeholders during the intervention period.
1.6. Long-term Follow-up: Long-term patient follow-up will be assessed by completion and dropout rates at each stage and qualitative feedback from patients and stakeholders during follow-up.
1.7. Study Timeline: The study timeline will be evaluated by measuring the time taken to recruit, complete the study, and conduct data collection and analysis across the study duration.
2. Intervention management and procedures
2.1. Adherence: Adherence to the turmeric intervention will be assessed through participant adherence data and qualitative feedback from participants and stakeholders during the intervention period.
2.2. Acceptability (Intervention): Acceptability of the turmeric intervention will be evaluated through qualitative interviews with participants and stakeholders during the intervention period.
2.3. Acceptability (Trial Design): Acceptability and appropriateness of the trial design will be assessed via qualitative interviews with participants and stakeholders during the intervention period.
2.4. Outcome Development: Development and understanding of primary and secondary outcomes for a future fully-powered study will be informed by analysis of quantitative outcome measures and participant feedback from qualitative interviews during the study.

Key secondary outcome(s))

The outcome measures that will be evaluated within this feasibility study are as follows:
1. Questionnaire Acceptability: Acceptability of the selected questionnaires and patients' willingness to complete them will be assessed through completion rate data and patient feedback from qualitative interviews during questionnaire administration.
2. Descriptive Statistics: Means and standard deviations of patient-reported outcome measures will be described through quantitative data analysis during the study.
3. Outcome Usefulness: Usefulness of study outcome measures will be evaluated by correlating quantitative outcomes with qualitative patient interviews during the study.
4. Sample Size Calculation: A sample size calculation for a future study will be developed using power calculations based on quantitative data collected during the study.

Completion date
01/01/2027

Eligibility

Key inclusion criteria
1. Patients due to receive radiotherapy (any regime), or concurrent chemoradiotherapy
2. Patients of any gender and 18 years or older
3. Patients willing to participate in the study and be randomised to one of the two treatment arms
4. Patients at least 2 weeks post-surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients unwilling to participate
2. Patients currently taking turmeric supplements
3. Patients allergic to turmeric
4. Patients unable to ingest capsules
5. Patients with oral lesions unrelated to the treatment or malignancy
6. Pregnancy and lactation

Date of first enrolment
02/01/2026

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Guys and St Thomas' NHS Foundation Trust - Cov Boost Covid19 Trials
249 Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
The Christie at North Manchester General Hospital
Department of Oncology
Nmgh
Delaunays Road
Manchester
United Kingdom
M8 5RB

Sponsor information

Organisation
University of West London

ROR
https://ror.org/03e5mzp60

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University College London Hospitals NHS Foundation Trust

Alternative Name(s)
University College London Hospitals, UCLH

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or anapysed during the study will be available upon request from John Hughes (john.hughes8@nhs.net)

IPD sharing plan summary
Available on request