

A clinic feasibility study to assess whether the use of two combined medicines (pentoxifylline and tocopherol) can prevent radiotherapy-related changes of the mouth and face compared to the current standard of care in the head and neck cancer population

Submission date 02/08/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/08/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/05/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

See <https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-treatment-prevent-radiation-fibrosis-radiotherapy-head-neck-cancer-can-cause-penve> (added 15/01/2021)

Contact information

Type(s)

Public

Contact name

Dr Vinod Patel

Contact details

Department of Oral Surgery
Floor 22
Guy's Tower Wing
Guy's Dental Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT
+44 (0)2071883885
vinod.patel@gstt.nhs.uk

Type(s)

Scientific

Contact name

Dr Gabriella Wojewodka

Contact details

OCRU Research Portfolio Manager
Oral Clinical Research Unit
Floor 25
Guy's Tower Wing
Guy's Dental Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT
+44 (0)207 188 7188 Ext 51980
gabriella.wojewodka@kcl.ac.uk

Additional identifiers**Clinical Trials Information System (CTIS)**

2018-001153-27

Integrated Research Application System (IRAS)

223295

Protocol serial number

1.0; CPMS: 40028

Study information**Scientific Title**

A prospective randomised controlled trial comparing the use of open-label pentoxifylline and tocopherol versus current standard of care for the prevention of fibrosis-related outcomes in irradiated head and neck oncology patients (feasibility study)

Acronym

PenVe

Study objectives

The use of pentoxifylline and tocopherol reduce radiation-induced fibrosis events such as osteoradionecrosis, trismus and dysphagia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/02/2019, London - Harrow Research Ethics Committee (Level 3, Block B Whitefriars Lewins Mead, Bristol, BS1 2NT, UK; Tel: +44 (0)20 7104 8057; Email: nrescommittee.london-harrow@nhs.net), ref: 18/LO/1910

Study design

Open-label two-arm randomised control trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Osteoradionecrosis (ORN) of the jaws, trismus and dysphagia following radiotherapy in patients with head and neck cancer

Interventions

Participants requiring head and neck radiotherapy as part of their standard treatment for cancer are randomised to one of two groups. Participants will be randomised in a 3:1 ratio (intervention: standard care) to enable better assessment of outcomes in the intervention group, including patient preference for drug formulation and the side effect profile. Randomisation will use permuted blocks of varying sizes and will be undertaken via a bespoke online randomization service provided by King's Clinical Trials Unit (KCTU). This is an open-label study. Neither patients, researchers nor statisticians will be blinded.

Both groups will continue to receive best standard of care in current practice, but group B will additionally receive pentoxifylline 400 mg BD and tocopherol 1000IU OD after their radiotherapy. Group B will also receive additional follow up calls. All participants will be in the trial for 6 months and have 4 study visits.

Maximum duration of treatment of a participant: 6 months.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Pentoxifylline, tocopherol

Primary outcome(s)

Feasibility of the trial:

1. Patient's preference of drug formulation and subsequent side effects, assessed through:
 - 1.1. Patient contact by daily telephone call in the first 2 weeks, 3 weekly telephone calls (+/- 1 week) in conjunction with patient diary, 3 monthly clinical follow up, 6 monthly clinical follow-up. This will be recorded in the patient notes and transcribed to the eCRF
 - 1.2. Independent and reflective patient feedback at focus groups
2. Recruitment and retention to the trial, and patient adherence to the drugs, assessed through:

- 2.1. Screening and enrolment log which is overseen by the PI and research nurse. The numbers consented and randomised will be recorded in the eCRF
- 2.2. Patient contact at 6 monthly clinical follow-up. This will be recorded in the patient notes and transcribed to the eCRF
- 2.3. Daily telephone call in the first 2 weeks, 3 weekly telephone calls (+/- 1 week) in conjunction with patient diary, 3 monthly clinical follow up, 6 monthly clinical follow-up. This will be recorded in the patient notes and transcribed to the eCRF
- 2.4. Independent and reflective patient feedback at focus groups
- 2.5. Vitamin E blood test taken at baseline, 3 months and 6 months
- 2.6. Patients asked to bring any remaining pentoxifylline and vitamin E for measurement of liquid or tablets left at formulation changeover and at month 6
3. Appropriateness and acceptability of the outcome measurement tools, assessed through completed questionnaires at trial visits and through focus groups

Key secondary outcome(s)

1. Presence of osteoradionecrosis assessed by clinical review including an oral examination at month 3 and month 6
2. Mouth opening measured using ruler at baseline, month 3 and month 6
3. Swallowing capacity assessed using Sydney swallow questionnaire at baseline, month 3 and month 6
4. Quality of life assessed using Washington quality of life questionnaire at baseline, month 3 and month 6

Completion date

30/09/2023

Eligibility

Key inclusion criteria

1. Patients (≥ 18 years) presenting with a primary head and neck (H&N) tumour requiring radiotherapy treatment and placing them in the highest risk group for developing osteoradionecrosis, trismus and dysphagia. These include:
 - 1.1. Oropharynx (tonsil, base of tongue)
 - 1.2. Nasopharynx
 - 1.3. Floor of mouth
 - 1.4. Lateral aspect of the tongue
2. Oncology treatment aiming for the intent to cure
3. Patients able to consent and willing to participate

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

54

Key exclusion criteria

1. Previous history of H&N cancer
2. Patients treated with any drug implicated to cause medication-related osteonecrosis of the jaw (MRONJ). These include bisphosphonates, denosumab, radium 223, tyrosine kinase inhibitors and bevacizumab
3. Any patient with significant medical history where taking part in this study may potentially compromise their health.
4. Women who are pregnant or breastfeeding or of childbearing age not on adequate contraception
5. Patients lacking capacity to consent
6. Oncology treatment for palliative care
7. Patients deemed to have a high risk of recurrent tumour
8. Patients with a previous history of cerebral haemorrhage, extensive retinal haemorrhage, acute myocardial infarction, severe cardiac arrhythmias and impaired renal function, impaired liver function which in the expert opinion of the principal investigator present a risk to the patient
9. Known drug allergy or sensitivity to pentoxifylline (or methylxanthines) and alpha-tocopherol or any constituents of the medication (e.g. methyl and propyl hydroxybenzoates or rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency)
10. Patients taking theophylline or oestrogens
11. Patients with metastatic disease
12. Patient participating in other drug (CTIMP) trials

Date of first enrolment

29/07/2019

Date of final enrolment

13/07/2022

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Guy's & St Thomas's NHS Foundation Trust
Fl 23, Oral Surgery Dept, Guy's Dental Hospital
London
United Kingdom
SE1 9RT

Sponsor information

Organisation

Guys & St Thomas NHS Foundation Trust

ROR

<https://ror.org/00j161312>

Funder(s)

Funder type

Government

Funder Name

Research for Patient Benefit Programme

Alternative Name(s)

NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

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

[Other unpublished results](#)

23/05/2025 No

No