ISRCTN79084153 https://doi.org/10.1186/ISRCTN79084153

Trismus RfPB trial: TheraBite® versus wooden spatula in the amelioration of trismus in head and neck cancer patients

Submission date
25/10/2012

Registration date
26/10/2012

Last Edited
26/10/2022

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

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

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-comparing-wooden-spatulas-therabite-device-head-neck-cancer-patients-mouth-opening-problems-trismus-trial

Contact information

Type(s)
Scientific

Contact name
Mr Colin Lunt

Contact details
Christie Hospital
550 Wilmslow Road
Manchester
United Kingdom
M20 4BX
+44 161 446 3000
colin.lunt@christie.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01733797

Secondary identifying numbers
13415

Study information

Scientific Title
Trismus RfPB trial: A randomised pilot study of TheraBite® use versus wooden spatula in the amelioration of trismus in head and neck cancer patients

Study objectives
Trismus is a tightening of jaw opening. The negative impact of trismus on the quality of life of head and neck cancer patients is well established. It affects eating, drinking, speaking and social function and is often as debilitating as any disfigurement resulting from treatment. The use of jaw exercises using a TheraBite® appliance following treatment has been shown to reduce the level of trismus in small studies. Many UK centres, however, use stacked wooden spatulas inserted between the incisors as a means of passive exercise. There is anecdotal evidence that suggests the use of exercises prior to treatment may help reduce the severity of the trismus experienced by the patient.

This study will enroll 112 head and neck cancer patients allocated by chance to use either the TheraBite® or wooden spatula, and patients will be asked to perform mouth exercises with either the Therabite or wooden spatula prior to and throughout their treatment. A review of the literature has suggested that use of passive mouth exercises could improve maximum mouth opening and hence QOL for these patients. Mouth opening will be the key outcome for the study measured over the time of treatments.

There is a need to evaluate both the effectiveness and cost-effectiveness of TheraBite® as opposed to wooden spatulas to evaluate whether they should be adopted as standard care in head and neck cancer patients. In this pilot trial, we will look at how well various questionnaires help us measure benefits of the TheraBite® to patients, as compared to usual care with wooden spatulas.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Greater Manchester North, First MREC approval date 01/06/2012, ref: 12/NW/0414

Study design
Randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Trismus in head and neck cancer patients

Interventions
TheraBite® is intended for use in individuals who are restricted in their ability to open their jaws (trismus or jaw hypomobility)

Wooden spatula, Wooden lollipop shaped sticks

Follow Up Length: 6 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Maximum mouth opening recorded daily

Secondary outcome measures
1. Patient compliance and tolerability measured at 3 and 6 months
2. Quality of Life and Health Economic outcome at baseline, 3 and 6 months

Overall study start date
23/11/2012

Completion date
25/06/2014

Eligibility

Key inclusion criteria
1. Provision of signed, written informed consent
2. Aged 18 years and older
3. Able to read and write English sufficiently to be able to complete questionnaires
4. Stage 3/4 oral and oropharyngeal cancer patients undergoing primary chemoradiotherapy or surgical free flap
pluspost operative radiotherapy or post operative chemoradiotherapy
5. All patients will receive 60-70 Gy in 30-35 fractions over 6 to 7 weeks to the region of the pterygoid muscles
6. All patients will have at least some trismus as indicated by subjective tightening in the jaw

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 112; UK Sample Size: 112

Total final enrolment
71

Key exclusion criteria
1. <12mm mouth opening (cannot use TheraBite®)
2. Anatomically unable to use Therabite for example patients who may only be partially dentate and to use the Therabite would place extreme stress on the existing teeth
3. Cognitive impairment as judged by the clinicians
4. International patients treated who will not have routine UK follow up
5. Previous surgery or radiotherapy (RT) to the head and neck prior to this diagnosis
6. Any patient who has no subjective tightening of the jaw

Date of first enrolment
23/11/2012

Date of final enrolment
25/06/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Christie Hospital
550 Wilmslow Rd
Manchester
United Kingdom
M20 4BX

Sponsor information

Organisation
Christie Hospital NHS Foundation Trust (UK)

Sponsor details
550 Wilmslow Road
Manchester
England
United Kingdom
M20 4BX

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03v9efr22

Funder(s)

Funder type
Government

Funder Name
NIHR (UK) - Central Commissioning Facility (CCF)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/03/2018	10/04/2019	Yes	No

Results article	results	01/05/2018	10/04/2019	Yes	No
Plain English results			26/10/2022	No	Yes