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The role of curcumin as a radiosensitiser in patients receiving radiation for head and neck squamous cell cancers and to find its effectiveness in reducing mucositis in patients receiving radiotherapy for head and neck squamous cell cancers

Submission date 30/10/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/11/2017	**Overall study status** Completed	
Last Edited 18/03/2020	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

Curcumin is the active ingredient in turmeric extract and can be used as a dietary supplement known for its anti-inflammatory (swelling) behaviour. It may be beneficial for patients undergoing radiotherapy or chemoradiotherapy for cancers affecting the head and neck. Radiotherapy uses high energy rays to destroy cancer cells. Chemoradiotherapy is a combination of radiation and chemotherapy medications together. It is thought that curcumin capsules could help reduce mucositis (a painful inflammation of the membranes in the digestive tract that is an adverse impact of radiotherapy). The aim of this study is to find out the benefit of administering curcumin capsule in patients receiving radiotherapy or chemoradiotherapy for cancers affecting head and neck.

Who can participate?

Adults aged 30-90 years old who are undergoing radiotherapy for head and neck squamous cell carcinoma.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive 500mg of curcumin three times a day until they complete their radiotherapy. Those in the second group receive a placebo until the completion of radiotherapy. Participants are followed up to measured their tumour response and for any side effects.

What are the possible benefits and risks of participating?

Participants may benefit from improvements in their symptoms. There is a slight risk of mild gastritis.

Where is the study run from?
R.L.Jalappa Hospital and Research Centre (India)

When is the study starting and how long is it expected to run for?
December 2012 to June 2014

Who is funding the study?
1. R. L. Jalappa Hospital and Research Centre (India)
2. Arjuna Natural Extracts Limited (India)

Who is the main contact?
Dr Arun P

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
SDUMC/ORLHNS/12P44002

Study information

Scientific Title
Efficacy of curcumin as a radio-sensitiser and in minimising mucosal damage in patients receiving radiotherapy for head and neck squamous cell cancers

Study objectives
To find out the Efficacy of Curcumin as a Radiosensitiser and in minimizing mucosal damage in patients receiving radiotherapy for head and neck squamous cell cancers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical committee of Sri Devaraj Urs Medical College and Research Center, 28/11/2012, ref: ECR /425/Inst/KA/2013/RR-16

Study design
Interventional single centre single blinded randomised study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adjunct to radiotherapy in patients with head and neck squamous cell cancer

Interventions
Detailed clinical examination are carried out and patients are staged according to AJCC 2012 TNM classification. All adult patients undergoing radiotherapy or concurrent chemo-radiotherapy for Head and Neck Squamous Cell Carcinoma are included in the study. All participants undergo biopsy for histopathological diagnosis. Other required tests are done such as: complete blood investigations, including liver and renal function tests, x-ray mandible, chest x-ray, electrocardiogram, were done. Written informed consent is taken from all the patients included in the study. Patients with Non Squamous Head and Neck cancers, not giving consent for the treatment, with severe acid-peptic disease, with distant metastasis and with recurrent tumors were excluded from the study.

All patients enrolled in the study are randomized using 4x4 block randomization. In this method four groups are made and allotted into 1,2,3,4 groups, then random numbers were generated from 1 to 4 using Research Randomizer. The patients are randomised into 2 groups - Study group (Group A) and Control group (Group B). Patients in group A received daily dose of 500mg of turmeric extract capsules thrice a day (total dose 1.5gm/day) and were asked to take after food, while patients in control group received placebo capsules thrice a day till the completion of radiotherapy. The patients started consuming the capsules on the first day of radiation till the completion of radiotherapy.

The turmeric extract (Biocurcumax, Arjuna Natural Extracts Ltd) contains 500mg of curcuminoid complex in powder form in hard gelatin capsule which is approved by FSSAI (Food Safety and Standards Authority of India) as a nutraceutical. The matching placebo capsule contained starch powder.

All the patients receive one fraction (2Gy) of radiotherapy per day, five times a week, for a total dose of 66 Gy, spinal cord was excluded after 46Gy. Patients planned for Chemoradiation received Cisplatin infusion (50mg/m2) weekly along with radiotherapy. They remain as inpatients during their entire course of treatment and a constant check was kept on their dental, medical parameters and supportive care was given to subjects of both the arms. Patients are asked to maintain a good oral hygiene.

Intervention Type
Supplement

Primary outcome(s)
1. Tumor response is measured using the RECIST criteria using contrast enhanced computerized tomography (CECT) scan at three months
2. Effect of curcumin on oral mucositis is measured using the NCI-CTAE and WHO criteria for mucositis on a weekly basis during treatment and 2 months after treatment for subjective and Objective Assessment respectively

Key secondary outcome(s))
There are no secondary outcome measures.

Completion date
01/06/2014

Eligibility

Key inclusion criteria
All adult patients undergoing radiotherapy or concurrent chemo-radiotherapy for Head and Neck Squamous Cell Carcinoma
2. Aged 30- 90 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
61

Key exclusion criteria
1. Patients with Non Squamous Head and Neck cancers, patients not giving consent for the treatment
2. Patients with severe acid-peptic disease
3. Patients with distant metastasis
4. Patients with recurrent tumors

Date of first enrolment
10/12/2012

Date of final enrolment
01/01/2014

Locations

Countries of recruitment
India

Study participating centre
R.L.Jalappa Hospital and Research Centre
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Tamaka
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Sponsor information

Organisation
Sri Devaraj Urs Medical College

ROR
https://ror.org/00k9e1m49

Funder(s)

Funder type
Not defined

Funder Name
R. L. Jalappa Hospital and Research Centre

Funder Name
Arjuna Natural Extracts Limited

Results and Publications

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. Arun.P, Email : docarunkmc@gmail.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/02/2020	18/03/2020	Yes	No