

PPALM - Palm oil and Pentoxifylline Against Late Morbidity

Submission date 08/01/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 12/01/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 12/08/2022	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-treatment-to-relieve-the-side-effects-of-radiotherapy-to-the-pelvis-ppalm>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT02230800

Clinical Trials Information System (CTIS)

2012-004211-31

Protocol serial number

17979

Study information

Scientific Title

Randomised double-blind controlled phase II trial of Tocovid SupraBio in combination with pentoxifylline (PTX) in patients suffering long-term adverse effects of radiotherapy for pelvic cancer

Acronym

PPALM

Study objectives

Aim: To test the benefits of oral Tocovid SupraBio (tocotrienols) with pentoxifylline (PTX) in patients suffering chronic gastrointestinal adverse effects following curative pelvic radiotherapy for cancer.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London-Central, 20/08/2014, ref: 14/LO/1122

Primary study design

Interventional

Study design

Randomised; Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Cancer; Subtopic: Colorectal Cancer, Bladder Cancer, Gynaecological Cancer, Prostate Cancer; Disease: Bladder (advanced), Bladder (superficial), Cervix, Ovary/Fallopian tube, Prostate, Rectum, Testis, Uterus/Endometrium, Vagina

Interventions

Randomisation: Treatment allocation will be in a 2:1 ratio of Tocovid SupraBio+PTX:Matched placebo and will be based on computer generated random permuted blocks.

Placebos, Matching placebos bd for 12 months; Tocovid SupraBio, 200mg po bd plus pentoxifylline (PTX) 400mg po bd for 12 months; Follow Up Length: 12 month(s)

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

1. Tocovid SupraBio 2. Pentoxifylline

Primary outcome(s)

1. Change at 12 months in the bowel disease subset of the Modified IBDQ Quality of Life questionnaire

Key secondary outcome(s)

1. Change at 12 months in rectal IBDQ bleeding score between the two groups in those patients presenting with grade 2, 3 or 4 bleeding
2. Change at 12 months in IBDQ faecal incontinence score between the two groups in those patients presenting with grade 1 or greater incontinence
3. Proportion of items graded as marked or severe (grade 3 or 4)
4. Physician assessment of rectal dysfunction based on the modified CTCAE Version 4 grading
5. Patient self-assessments: QLQ-C30 and CR29 and the Gastrointestinal Symptom Rating Scale
6. Photographic assessment of rectal mucosa
7. Serum fibrosis marker levels

Completion date

20/12/2019

Eligibility**Key inclusion criteria**

1. Age over 18 years.
2. Past history of a malignant pelvic neoplasm (T14 N02 M0) of the rectum, prostate, testis, bladder, uterine cervix, uterus, vagina, anal canal or ovary.
3. A minimum 12 months followup postradiotherapy (24 months for patients with past history of stage T4 and/or N2 disease)
4. A maximum 7 years postradiotherapy
5. No evidence of cancer recurrence
6. Gastrointestinal symptoms attributable to prior radiotherapy: grade 2 or higher in any CTCAE Version 4 category, or grade 1 with difficult intermittent symptoms
7. Symptoms are not relieved by appropriate lifestyle advice and medication over a 3 month period
8. Physical and psychological fitness for Tocovid SupraBio+PTX therapy
9. Written informed consent and availability for follow up
10. Willingness to keep to a specified level of dietary fat intake during the study
11. Symptoms are not relieved by appropriate life-style advice and medication over a 3-month period after optimal gastroenterological assessment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

62

Key exclusion criteria

1. Surgery for rectal cancer
2. Contraindication or other inability to undergo magnetic resonance imaging, if required to rule out malignancy
3. Dietary supplementation containing alphetocopherol above a daily dose of 30mg at any time during the last three months
4. Medication with pentoxifylline at any time since radiotherapy
5. Pregnancy or breast feeding
6. Ischaemic heart disease, uncontrolled hypertension, hypotension, acute myocardial infarction, cerebral haemorrhage, retinal haemorrhage, renal failure, liver failure and medication with insulin, ketorolac or vitamin K
7. Allergy to soya
8. Known hypersensitivity to the active constituent, pentoxifylline other methyl xanthines or any of the excipients', as per SmPC for pentoxifylline

Date of first enrolment

25/11/2014

Date of final enrolment

05/01/2017

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Royal Marsden Hospital

Academic Radiotherapy Department

Downs Road

Sutton

United Kingdom

SM2 5PT

Sponsor information**Organisation**

Royal Marsden NHS Foundation Trust

ROR

<https://ror.org/0008wzh48>

Funder(s)

Funder type

Government

Funder Name

Malaysian Palm Oil Board (Malaysia)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed are available on request from the PPALM trial PI, Dr Alexandra Taylor (Alexandra.taylor@rmh.nhs.uk), via completion of a data access request form after such time that the primary analysis publication and any other key analyses have been completed.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2022	11/02/2022	Yes	No
Basic results		12/12/2020	10/01/2022	No	No
HRA research summary			26/07/2023	No	No
Protocol file	version 6.0	26/06/2017	12/08/2022	No	No