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PPALM - Palm oil and Pentoxifylline Against Late Morbidity

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

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

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Additional identifiers

Clinical Trials Information System (CTIS)
2012-004211-31

ClinicalTrials.gov (NCT)
NCT02230800

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

Study design
Randomised; Interventional

Primary study design
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 alphatocopherol 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
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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
Participant information sheet	Participant information sheet version 6.0	11/11/2025	11/11/2025	No	Yes
Protocol file		26/06/2017	12/08/2022	No	No