

PPALM - Palm oil and Pentoxifylline Against Late Morbidity

Submission date 08/01/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/08/2022	Condition category Cancer	<input type="checkbox"/> 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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Contact details

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Additional identifiers

EudraCT/CTIS number

2012-004211-31

IRAS number

ClinicalTrials.gov number

NCT02230800

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

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 measure

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

Secondary outcome measures

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

Overall study start date

26/07/2012

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 117; UK Sample Size: 117; Description: 99 patients will provide 85% power to detect a difference in Modified Inflammatory Bowel Disease Questionnaire bowel subset score of 7.5, which is considered a worthwhile improvement in response to 12 months of Tocovid SupraBio+PTX compared to placebo. 117 patients will be recruited to allow for a 15% drop out rate.

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**

England

United Kingdom

Study participating centre

Royal Marsden Hospital

Academic Radiotherapy Department

Downs Road

Sutton

United Kingdom

SM2 5PT

Sponsor information

Organisation

Royal Marsden NHS Foundation Trust

Sponsor details

Fulham Road

London

England

United Kingdom

SW3 6JJ

Sponsor type

Hospital/treatment centre

ROR

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

Funder(s)

Funder type

Government

Funder Name

Malaysian Palm Oil Board (Malaysia)

Results and Publications

Publication and dissemination plan

To be confirmed at a later date

Intention to publish date

31/12/2020

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?
Basic results	version 6.0	12/12/2020	10/01/2022	No	No
Results article		01/03/2022	11/02/2022	Yes	No
Protocol file		26/06/2017	12/08/2022	No	No
HRA research summary			26/07/2023	No	No