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| **Full Study Title:** | COLO-PREVENT – A phase 2/3 randomised platform trial assessing the efficacy of aspirin, aspirin plus metformin, or resveratrol, for colorectal polyp prevention in patients undergoing surveillance in the Bowel Cancer Screening Programme |
| **Short Study Title:** | COLO-PREVENT: A platform for developing COLOrectal cancer PREVENTion therapies |
| **IRAS ID:** | 1005142 |
| **EudraCT:** | 2022-000531-23 |
| **Chief Investigator**: | Professor Anne Thomas |
| **Sponsor:** | University of Leicester (Ref: 0834) |
| **Date first site opened:** | December 2022 |

**Key Site Contact Details**

|  |  |
| --- | --- |
| Name of Participating Site: |  |
| Address of Participating Site: |  |
| Name of BCSP Centre |  |

|  |  |
| --- | --- |
| Name of Principal Investigator: |  |
| Work address of PI: |  |
| Telephone number: |  |
| Email address |  |

|  |  |
| --- | --- |
| Name of Research nurse / Specialist Screening Practitioner (SSP): |  |
| Telephone number: |  |
| Email address |  |

**Research and Development/Research and Innovation Contact Details**

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| --- | --- |
| Name of Capacity and Capability contact: |  |
| Telephone number: |  |
| Email address |  |

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| --- | --- |
| Name of Contract Officer: |  |
| Telephone number: |  |
| Email address |  |

**Pharmacy Contact Details**

|  |  |
| --- | --- |
| Name of Trial Pharmacist: |  |
| Address of dispensing pharmacy: |  |
| Email address |  |
| Telephone number: |  |

**Patient population and recruitment**

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| **1** | Were previous recruitment targets met for similar trials? |  |
| **1a** | Number of patients with high risk findings identified at your Bowel Cancer Screening Centre per year: |  |
| **1b** | Of these, how many do you anticipate would be eligible for the study? |  |
| **1c** | How many patients do you anticipate your site will recruit per year? |  |

**Standard of care**

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| --- | --- | --- |
| **2** | Describe the patient pathway for patients with high risk findings within your BCSP Centre: | |
| **3** | Would your colleagues agree to their patients being prescribed the trial drugs?  (**Main trial**: aspirin 75mg OD, metformin 500mg BD)  (**Sub-trial**: 5mg or 1g resveratrol or placebo) | YES/NO |

**Resources**

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| --- | --- | --- | --- |
| **4** | Do you have experience of recruiting to drug trials?  If yes, detail number of trials\_\_\_\_\_\_\_. | | |
| **5** | Did you recruit to target? | | YES/NO |
| **6** | Do you have current or potential new trials that will compete or affect recruitment into this trial? | | YES/NO |
| **7** | If yes, please specify trial names below: | | |
| **8** | How many co-investigators will be involved at your site?  *(NB: a co-investigator is another physician who will work alongside you on the trial and take full responsibility in your absence)* | |  |
| **9** | Will a Specialist Screening Practitioner or Research Nurse lead on screening, recruitment, and other research tasks at your site? | | SSP/RN |
| **9a** | Do they have clinical trial experience? | | YES/NO |
| **10** | For this type of CTIMP can informed consent be taken by a delegated SPP/RN in your Trust? | | YES/NO |
| **11** | Do you and your research team have the capacity to support this trial? | | YES/NO |
| **12** | In which form are your medical records? | Paper  Electronic | YES/NO  YES/NO |
| **13** | Is there office space available for trial monitoring by a member of the coordinating centre/sponsor? | | YES/NO |
| **14** | Do you have archiving facilities for trial documentation for at least 25 years? | | YES/NO |

**Trial Specific Procedure Facilities**

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| **15** | Do you have adequate facilities and equipment to accommodate the trial?   * Patient/research area * Laboratory processing of blood, fresh tissue, and urine samples * Taking of rectal biopsies during colonoscopy procedure * ECG | |
| **15a** | If not, how will you access facilities/equipment? | |
| **16** | Do you have a -80oC freezer to store samples? | YES/NO |
| **17** | Are procedures for equipment temperature and calibration in place? | YES/NO |

**Additional information**

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| --- | --- | --- |
| **18** | Are you able to support ***all*** the requirements of the COLO-PREVENT trial? | YES/NO |
| **18a** | If not, please detail any potential problems below and how we could help to solve them? | |

**General set up information**

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| **19** | How long does your capacity and capability assessment take? | |
| **20** | Are there any local groups or committees that the trial must be submitted to?  If yes, please detail below (including timeframes). | |
| **21** | Does your organisation use Edge? | YES/NO |

**THANK YOU FOR COMPLETING THIS QUESTIONNAIRE**

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| --- | --- |
| Feasibility form completed by: | |
| Name (print): |  |
| Job title: |  |