Protocol

|  |  |
| --- | --- |
| **Study Title:** |  |
| **Chief Investigator:** |  |
| **Sponsor:** |  |
| **Funder:** | [if applicable] |

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# Study Summary:

|  |  |
| --- | --- |
| **Overall Aim:**  |  |
| **Primary Objective:** |  |
| **Secondary Objective** |  |
| **Target Accrual:** |  |
| **Inclusion & Exclusion Criteria:** |  |
| **Data Collection Summary:** |  |
| **Anticipated Duration of Recruitment:** |  |
| **Duration of Participant Follow-up:** |  |

# Background

# Aims and Outcomes

## Primary Objective

## Secondary Objective

## Primary Outcome Measure

## Secondary Outcome Measure

# Selection of Participants

## Inclusion criteria

## Exclusion criteria

## Screening and Informed Consent process

[i.e. how will you identify potential participants and check whether they meet the eligibility criteria? How will you confirm someone’s consent to participate? (normally would provide a participant information sheet and consent form)]

# Study Procedures

## Study pathway flowchart

[insert diagram flowchart]

## Detail of procedures and timescales

[provide full break down – i.e. when each study visit takes place, whether this is on site or virtual, what happens at each timepoint, how different is the activity compared to usual care, etc]

# Data Collection

## Overview of data items to be collected

[Ensure to mention if any personal data items such as age, D.O.B, sex, ethnicity, etc]

## Data collection methods

[Mention is using a study-specific data collection proforma (aka ‘case report form’] and if electronic or paper-based, where stored, any databases involved, etc]

## Timelines for collecting and submitting data

[E.g. At which points during the study / each participant’s pathway will the above info be collected? How quickly does it need to be collated and returned?]

## Confidentiality arrangements

[E.g. How will relevant data be securely collected and (if required) transferred to lead site/analyst? How will access be limited?]

## Review of data completeness and data queries

[What process is in place for check data collection completeness and to watch out for any errors? Will you be carrying out data query reports?]

# Statistical Analysis Plan

## Justification for sample size

## Planned analysis

# Safety Reporting and Protocol Deviations

## Definitions of Adverse Events (‘AEs’) and Adverse Reactions (‘ARs’) and Protocol deviations

[There is a definition of Adverse Events/Reactions here which may be useful: <https://ctep.cancer.gov/protocoldevelopment/electronic_applications/ctc.htm> - also can consult R&D safety reporting SOP for relevant info to include here]

## Reporting procedures

Potential adverse events/reactions or Protocol deviations should be promptly reported to the Sponsor and Chief Investigator using the relevant study-specific reporting form. The Sponsor and Chief Investigator would then review the details to assess any impact on participant safety and the research dataset quality requiring ‘corrective action(s)’ and also to assess if there are learning points to inform ‘preventative action(s)’ to help prevent a recurrence. The study team will abide by the NHS Health Research Authority’s guidelines for safety reporting to the HRA and NHS research ethics committee as well as all applicable SOPs from the sponsor organisation.

# Sample Size

## Number of participants and records

## Statistical analysis plan

# Study Management and Sponsorship Oversight

## Study management arrangements

A ‘study management group’ comprising key study team members and independent personnel has been created to monitor study progress and agree ongoing actions. This group will meet periodically during the study.

## Sponsorship and monitoring arrangements

The sponsor’s separate monitoring plan document provides guidance on the planned monitoring activities by the sponsor and the supporting rationale.

# Withdrawal of Participants from Study

## Handling withdrawal requests

Participants will be free to withdraw from the study at any point; this point will be communicated in the Participant Information Sheet.

## Use of data following withdrawal

[Explain whether would keep all data received to date or would discard]

# Study Funding

[Explain whether the study is being funded through a grant]

# Publication and Dissemination Plans

## Publication and presentations

The results will be presented locally, nationally and internationally; where any personal information is necessary for the data analysis (e.g. use of demographic data) this will be presented in a way to ensure that individuals cannot be identified and the patients will be informed in advance of giving their consent to participate in the study.

## Enhanced dissemination

[Any ideas for different kinds of dissemination to connect with wider range of audiences and/or in a particularly innovative way e.g. use of video, audio, online, etc]

# References