**Protocol Title**

Version Number:

Date of Protocol:

SYNOPSIS

Protocol title:

Protocol version:

LIST OF INVESTIGATORS

Principal Investigator:

Organisation

Address:

Telephone no.:

Fax no.:

Email

Co Investigator:

Organisation

Address:

Telephone no:

Fax no.:

Email

**Summary**

Study title:

Protocol version

Objectives Primary objective

Secondary objectives

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Planned sample size

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***[Please note all sections may not be relevant to your study design delete / include as necessary, the sections marked with \* are essential for all studies]***

# BACKGROUND

## Disease Background\*

Based on literature review and investigators' experiences, brief history of the disease including prognostic factors. All references must be listed at the back of the protocol.

## Rationale for Performing the Study\*

State clearly why you wish to do the study, what are you looking for, what would you like to achieve.

Hypothesis

# STUDY OBJECTIVES\*

## Primary Objective\*

## Secondary objectives

# STUDY Design\*

## Design\*

* For example a randomised control trial, qualitative study, case control study etc.

## Study Groups

## number of participants\*

## number of centres

* Enter the number of centres and the expected number of participants at each centre
* If the study involves a number of centres, do all the centres perform the same procedures?

## duration

* The study duration (foreseen start date and end date).
* Include the expected time period for the recruitment phase of the study

# Participant section

## Inclusion Criteria\*

For example but not limited to:

\* Sex:

\* Age range:

\* Weight:

\* Height:

\* Disease status:

\* Concomitant disease status:

\* Laboratory parameters:

\* Others: radiograms, electrocardiograms, CT-scan, ultrasound, etc.

\* Willingness to give written or oral informed consent. (delete either written or oral, as appropriate) and willingness to participate to and comply with the study.

## Exclusion Criteria\*

For example but not limited to:

\* Women lactating, pregnant or of childbearing potential who are not willing to avoid becoming pregnant during the study.

\* Patients with a history of XXXX disease(s) that is (are) likely to interfere with the metabolism or excretion of the test medication.

\* Patients who had received an investigational new drug within the last XX days/weeks.

\* Patients with a history of a psychological illness or condition such as to interfere with the patient's ability to understand the requirements of the study.

\* Patients with XXXX disease that is likely to interfere with the evaluation of the patient's safety and of the study outcome.

\* As the following medication(s) can have interactive effects and may interfere with the patient's ability to meet the study requirements, they cannot be administered during the clinical study. (list the prohibited concomitant medications, here)

# STUDY Outline\*

## Study Flow Chart

Diagram of the study design (example below)

Identification of potential participants

Screening/ consent

Enrolment

Randomisation

Treatment Phase

(e.g. 12 weeks)

Group A Group B

Follow up Follow up

## Investigation plan\*

Include all study visits and all study procedures at each visit. This information could be displayed in a table.

Example below

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| List Interventions | Enrolment Visit | Visit 1 | Visit 2 | Visit 3 | Final Study Visit |
| Informed Consent | ✓ |  |  |  |  |
| Inclusion / Exclusion critieria | ✓ |  |  |  |  |
| Physical examination |  | ✓ |  |  |  |
| CXR |  |  |  |  |  |
| Adverse Event & Serious Adverse Event Assessment |  | ✓ | ✓ | ✓ | ✓ |

Explicitly describe how study activities/ procedures differ from normal/standard care, and what procedures are additional to normal/standard care.

If a study procedure is not performed as per normal practice, please outline how the procedure will be performed for this study.

## Study Procedure Risks\*

## Recruitment and Screening\*

Explain how and where potential participants will be identified for the study, and by whom. It is important to describe how any pre-existing relationship between participants and treating staff will be managed (e.g. how is the possibility of coercion managed where a patient’s treating clinician is recruiting?)

Examples may include the following:

* review of databases (please identify the database and the custodian)
* review of outpatient clinic files, Emergency Department admissions, inpatients (please include who will be reviewing the notes e.g. research coordinator)
* advertisements (include where the advertisement will be e.g. newspaper, poster in outpatients area or hospital foyer, radio announcements)
* Information Letter to Medical practitioners

Explain how potential participants will be screened for the study.

## Informed Consent Process\*

Explain the process and how the process will be documented.

## Enrolment Procedure\*

Explain how a potential participant will be enrolled into the study.

An example: The participant will be enrolled into the study after the informed consent process has been completed and the participant has met all inclusion criteria and none of the exclusion criteria. The participant will receive a study enrolment number and this will be documented in the participant’s medical record and on all study documents.

## Randomisation Procedure

As relevant, explain how the participant will be randomized.

An example: The participant will be randomized at study visit X after they have met the randomization criteria (e.g. baseline enrolment bloods are within normal range and the CT Scan confirms disease). At this visit the participant will be randomised to study procedure A or Study procedure B, and receive a Randomisation Number allocated by pharmacy

# SAFETY\*

## Adverse Event Reporting\*

Provide a definition (e.g. Any untoward medical occurrence in a participant which does not necessarily have a causal relationship with the study treatment. An adverse event can therefore be any unfavorable or unintended sign, symptom or condition and/or an observation that may or may not be related to the study treatment.)

## Serious Adverse Event Reporting

Provide a definition (e.g. Any untoward medical occurrence that results in the following: death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability/incapacity or congenital/birth defect, condition requiring unnecessary medical or surgical intervention.

For device studies the following should be included: an adverse event that might have led to death or a serious deterioration in health had suitable action or intervention not taken place:

1. A malfunction of device such that it has to be modified or temporarily/permanently taken out of service
2. A factor found on examination of the device (a deterioration in characteristics or performance)

## Data Safety and Monitoring Board

## membership and responsibilities

## Early Termination

What are the possible circumstances for early termination of the study and how will this be managed ie who is responsible for what aspect in the process of terminating the study (informing participants, correspondence to HREC, compiling a final study report, unbinding if applicable).

# BLINDING AND UNBLINDING

As relevant, describe how the study will be blinded.

# STATISTICAL CONSIDERATIONS\*

Sample Size or Power Calculation\*

Statistical Analysis Plan\*

# STORAGE AND ARCHIVING OF STUDY DOCUMENTS\*

# REFERENCES\*

## References to national and international guidelines on the conduct of research in humans\*

# APPENDICES

Advertisement(s)

Data collection sheet / Case Report Form

All protocol-specific appendices