Study Protocol

**Study Title:**

**Study Acronym:**

**Phase of Development:**

**Protocol Number:**

**Protocol Version and Date:**

**EudraCT Registry Number:**

**ClinicTrials.gov Registry Number:**

**Indication:**

**Investigational product**:

**Sponsor:**

**Coordinating/Principal Investigator:**

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# PROTOCOL SIGNATURE PAGE

**Protocol Version and date:**

**Protocol Title:**

**Sponsor:**

**Principal Investigator:**

I agree:

* to assume responsibility for the proper conduct of this study
* to conduct the study in compliance with this protocol and any future amendments
* not to implement any deviations from or changes to the protocol without prior review and written approval from the Ethics Committee, except where necessary to eliminate an immediate hazard to the subjects, or for administrative aspects of the study (where permitted by all applicable regulatory requirements)
* that I am thoroughly familiar with the appropriate use of the investigational drug, as described in this protocol
* to ensure that all persons assisting me with the study are adequately informed about the investigational drug and their study-related duties and functions as described in the protocol
* that I am aware of and will comply with the current good clinical practice (GCP) guidelines and ethical principles outlined in the Declaration of Helsinki
* to conduct the study in accordance with all applicable laws and regulations

Printed name Signature Date

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# Trial Registration/Protocol Summary

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| **Information** | |
| EudraCT number:  Date of registration: |  |
| Clinical Trial  Authorization (CTA) from FAMHP (FAGG)  Date of approval: |  |
| ClinicalTrials.gov: |  |
| Official Title: |  |
| Study Phase/Type: |  |
| Condition: |  |
| Objectives: |  |
| Investigational Product: |  |
| Interventions: |  |
| Endpoints: |  |
| Study population: |  |
| Number of patients: |  |
| Overview of  study design: |  |
| Statistical  Considerations: |  |
| Sponsor: |  |
| Country(ies) of  Recruitment: |  |
| Inclusion Criteria: |  |
| Exclusion Criteria: |  |
| Date of first  enrolment: |  |
| Target sample size: |  |

# Protocol Version History

|  |  |  |
| --- | --- | --- |
| **Version No.** | **Approval Date Lead EC** | **Release Date** |
|  |  |  |
|  |  |  |
|  |  |  |

# Sponsor/Coordinating Investigator Information

Coordinating Investigator

Sponsor

Principal Investigator

Co-investigators

Additional co-researchers

Statistician

Laboratory (ies)

Pharmacy

Study Coordinator

Study sites and co-investigators

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