Abbreviations

EC Ethics Committee

ICF Informed consent form

MRI Magnetic resonance imaging

1 Preamble

2 Protocol

2.1 Introduction

2.1.1 Background

2.1.2 Geographic context

2.2 Study objectives and Endpoints

2.3 Study design

2.4 Subject selection

2.4.1 Study population and Eligibility

2.4.2 Inclusion criteria

2.4.3 Exclusion criteria

2.5 Subject accountability

2.5.1 Point of enrollment

2.5.2 Withdrawal

2.5.3 Lost to follow-up

2.5.4 Subject status and classification

A subject will be considered enrolled in this study at the time of the study-specific Informed consent form (ICF) execution.

2.5.5 Enrolment control

The overall enrollment in the study will be capped at 1000 participants.

2.5.6 End-of-study definition

The study is considered complete when 20 years from the first enrolment are over.

2.6 Study methods

2.6.1 Candidate Screening

Subjects will be screened for participation in the study based on study Inclusion and exclusion criteria as listed in Section 2.4. Subjects who have provided informed consent and who have been determined to not meet all eligibility requirements will be withdrawn.

2.6.2 Informed consent

Written informed consent must be obtained from potential study candidates and enrollment is only valid, after subjects sign and date the ICF.

- Subjects will be asked to sign the ICF before study-specific tests or procedures are performed;
- The idea of the study must be explained, and subjects must be given the time and opportunity to ask questions and have those questions answered to their satisfaction.
- The ICF is study specific and has been approved by theEthics Committee (EC).
- Written informed consent must be recorded appropriately by means of the subject's dated signature.

2.7 Statistical considerations

2.8 Data management

2.9 Amendments

In case of protocol changes possibly affecting the rights, safety or welfare of any subjects or scientific integrity of the data, a protocol amendment will be completed. Appropriate approvals (especially from the EC) of the revised protocol must be obtained prior to its implementation.

2.10 Compliance

2.10.1 Statement of Compliance

This study will be conducted in accordance with ICH-GCP and with the ethical principles originating in the Declaration of Helsinki.

2.10.2 Investigator responsibilities

Delegation of responsibilities

2.10.3 Ethics committee

2.11 Monitoring

2.12 Potential Risks and Benefits

2.12.1 Anticipated Adverse Events

2.12.2 Risks associated with the study participation

2.12.3 Risks associated with the Magnetic resonance imaging (MRI)

2.13 Safety Reporting

2.14 Informed consent

2.15 Suspension or termination of the study

2.16 Study registration and Results

2.17 Bibliography

3 Appendix