Patients/Controls Recruitment and Questionnaires Administration in the Euro-MOTOR Study

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A. Scope and applicability

The purpose of this SOP is to describe the instructions for the enrolment of patients or controls and the administration of questionnaires for the Clinical Coordination workpackage (WP-2) and Exposomics (WP-7) of Euro-MOTOR.

B. Introduction

The objective of Euro-Motor is to discover new causative and disease-modifying pathways to pave the way for novel therapies. This will achieved by generating large scale data set and integrating these data in a validated computational ALS model.

This SOP aims to explain the design and administration of EuroMotor questionnaires consisting in a standardized and validated collection of epidemiological, clinical and neuropsychological data obtained from patients and controls.

C. Recruitment

In Euro-Motor two questionnaires will be used. The first questionnaire has to be completed by the examiner and the second has to be completed by the case or by the control.

Blood and urine will be collected at the time of administration of the questionnaires for WP-2 and WP-7 (see *Standard Operating Procedure for Collection of Blood and Urine Samples*).

(I) Patient recruitment

All patients from local population-based ALS registries (diagnosed from Jan 01 2011), with probable, probable laboratory supported, possible or definite EE category are eligible for inclusion.

They should be informed in person (e.g. on the occasion of a visit) or by telephone at home.

After that, provide the patient (directly or by mail/email) with the information leaflet, the privacy information sheet and the informed consent form.

To be enrolled, the patient must give the informed consent signed by him/her or by a family member if the patient is unable to sign.

(II) Control recruitment

Age, gender and geographically matched controls are to be recruited.

For each registered case, 1 normal individuals will be selected from the lists of the general practitioners living in the case's geographic area, matched on gender and age (± 2.5 years).

Controls should be contacted by their general practitioners and informed by Euro-Motor examiner telephonically at home.

After that, provide the controls (directly or by mail/email) with the information leaflet (for control), the privacy information sheet and the informed consent form.

To be enrolled, the control must give the informed consent signed by him/her.

D. Materials (per subject)

- Examiner Questionnaire
- Patient or Control Questionnaire

- Consent Form for Questionnaire
- Consent Form for Genetic Analyses
- Information Leaflet for patient or control
- Privacy Information Sheet
- Verbal Fluency Test Sheet
- Chronometer (for neuropsychological tests)
- Measuring-tape (for waist circumference measurement)

E. Questionnaire administration

Before the questionnaires administration, verify that the patient/control has read the information leaflet and signed the Euro-Motor consent form.

Patients and controls should be matched and questionnaires should be undertaken in an identical manner.

(I) Examiner questionnaire

The examiner part of the questionnaire consists of the collection of clinical/genetic data and neuropsychological testing.

The clinical/genetic part should be taken only in the case of patients while the neuropsychological tests should be performed by both patients and controls.

The clinical part of the questionnaire should be completed as soon as possible after the date of diagnosis (only for patients).

For both patients and controls the neuropsychological part should be completed as soon as possible.

(II) Patient/Control questionnaire

The patient or control questionnaire contains many questions about different proposed risk factors for ALS. This collection of data about lifestyle, use of drugs/substances, family history, etc., is completed by the respondent in written format.

(III) Mode of Patient/Control questionnaire administration

If possible, give to patient/control (directly or by mail/email) the questionnaire 2 weeks before the day of interview/data collection.

There are 3 types of interactions for every patient and control in order to complete the data collection.

1. Face-to-face interview (including blood and urine collection)
2. Interview by telephone (completely or in part)
3. Self-administered questionnaire (compiled -completely or in part- without the presence of the examiner).

The face-to-face interview (1) is the standard.

You should employ options (2) and (3) only in case of need.

Inform also the patient/control that he/she has 2 weeks to report (by telephone or email) on integrations or modifications of data collection.

F. Follow-up and revision

In the two weeks after questionnaire administration, the examiner should verify the collection for missing data, errors or misunderstandings, contacting the patient/control by telephone at home in case of problems.

This 2-week follow-up period is also available to patient/control to report integrations or modifications of data collection (see above).

G. Validation and conclusion of questionnaires

After the two weeks of follow-up, the examiner can validate the questionnaires.

Each questionnaire should contain the euronumber ID (code that will include: the center, the country, the subject).

In the clinical part of examiner questionnaire, the “Date of checking endpoint” is the date of questionnaires conclusion (as reference for death, tracheostomy or NIV>23hr/day).

The only exception to questionnaire conclusion is the “Change of diagnosis other than ALS/MND”. This possibility should be monitored and, in that case, reported in the questionnaire.