



GeroCovid Observational Study

Principal Investigator Prof. Raffaele Antonelli Incalzi

ABSTRACT dated April 15, 2020 - FV 1.1

1. Background and purpose

The Italian Society of Gerontology and Geriatrics (SIGG) is establishing a clinic-epidemiologic unit focused on Covid-19 in the elderly.

2. Aim

Overarching Objective

To assess age related variant presentation, risk profile, residual effects and final outcomes. It also aims at promoting good practices in each setting and overall in geriatric care during Covid-19 pandemic.

Specific Sub-Protocol Objectives

Indeed, SIGG has implemented a multidomain recording strategy GeroCovid data base allowing track the pandemic by Covid-19 and its effects on the geriatric population in different settings:

1. **«Acute patients ward»:** to define the risk profile and clinical presentations according to age and comorbidity;
2. **«Nursing Homes (RSA)»:** to measure the impact of preventive measures on the well-being of guests, in terms of:
 - a. prevention of the risk of contagion and effects on the emotional, neuropsychological level, etc;
 - b. to follow the dissemination and promotion of good practices, which are precisely the results of the measures adopted;
3. **«Home and outpatient care»:** to measure the impact of social distancing measures on personal well-being and on the quality of patient's care while promoting tele-consulting and remote monitoring;
4. **«Dementia outpatients»:** remote monitoring and evaluation of the effects of tele-prescriptions on disease control;



5. «**At home/Social Determinants**»: studying the impact of the Covid-19 on the health status, physical and cognitive efficiency, affective/mood state and housing conditions;
6. «**Outcomes**»: assessing the residual signs and symptoms and more in general the overall outcomes of Covid-19 on the geriatric population based on its frailty status and comorbidity profile.

And more specifically:

Acute patients ward

- **Observe & describe the clinical presentation**: current literature the information concerns the average of patients without focusing on multimorbid and variously disabled elderly people in whom it is known that the presentation of many acute, infectious and non-infectious diseases is often different from the canonical one.
- **Filling the gap of fundamental knowledge** for the correct and timely diagnosis in the most vulnerable population.
- **Defining the risk profile**: will make it possible to adopt the principle of proportionality, but also the timeliness of treatment rationally, avoiding approximate choices based on single and questionable criteria.

Nursing Homes (RSA)

- **Measuring the impact of preventive measures** on the well-being of guests, in terms of:
 - a. prevention of the risk of contagion and effects on the emotional, neuropsychological level, etc;
 - b. determine the impact of the measures adopted on the outcomes;
 - c. follow the dissemination and promotion of good practices, which are precisely the results of the measures.

Home and outpatient care

- To **cancel substitute initiatives** (telephoning, video calling, telematic prescription, remote monitoring of individual parameters ...) and will **assess their effectiveness**.
- To evaluate the impact of Covid-19 on the conditions of geriatric patients and to **identify negative and positive predictors** of the evolution of their health status.



Dementia outpatients:

- Monitoring the **effects of the Covid-19 emergency on the affective and cognitive state** of geriatric patients and **the level of plasticity of the management system**.
- **Identifying the risk factors for psychiatric decompensation** and thus make it possible to identify patients to be subjected to close monitoring, by grading the monitoring according to the real needs.

At home/ Social Determinants

- To **understand the real extent of the disease in that subpopulation** in terms of outcomes.
- To **quantify its impact on the health status**.
- To **define the predictors of the major outcomes**.

Outcomes

- **Assessing the residual signs and symptoms** e.g. permanent sequelae.
- **Assess clinical worsening or improvement or mortality** based functional determinants and comorbidity.

3. Patient selection and inclusion

- Minimum number of 120 sequential cases observed in the participating centres;
- Women or men >60 y at risk of Covid-19;
- Ideally patients should be identified prospectively. Retrospective cases continuing prospectively. Retrospective cases observed after March 1st, 2020;
- Exclusion criteria: no Informed Consent signed or explicit opting-out (pts specifically express their dissent);

Primary Endpoint: clinical follow up and status according to WHO criteria at 14, 30 and 60 days.

4. Methodology

The GeroCovid Observational e-registry can be deployed in EU and UK countries. The GeroCovid Observational Study will be conducted in each centre according to the Good Clinical Practice and only after the approval of the Bio-Ethics committee geographically competent.



Bluecompanion, a companies' group specialized in digital solutions for regulatory compliant Clinical Trials, is making available a web-based digital platform in English to Investigational Sites adhering to the protocol. The platform is specifically designed to capture data on: 1) the Investigational Centre characteristics; 2) the geriatric patients' clinical evolution during Covid-19 pandemic.

More than 100 centres are expected taking part in Europe. Each centre will maintain the ownership of its own data, besides contributing to the whole data collection. Any contributor will propose the analyses of data according to a project approved by the Scientific Advisory Board. A biostatistical team will coordinate data analyses in order to ensure methodological consistency.

5. Gerocovid Observational Study expected fall out/benefits

- ✓ Better **definition of nosology in the geriatric population**, the one at greatest risk;
- ✓ Consequent immediate effects on patient **treatment modalities**;
- ✓ **Knowledge** of outcomes and related care, health and social needs;
- ✓ Definition of **best practices** in high risk settings;
- ✓ **Corpus of information** to rationally favour health planning in the event of future crises;
- ✓ **Development of a network** that can be activated on call for healthcare purposes.