

**PASSIVE MOBILIZATION AND VASCULAR FUNCTION**

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**OPINION REQUEST TO THE INDEPENDENT ETHICAL  
COMMITTEE OF THE NEUROLOGICAL,  
NEUROPSYCHOLOGICAL, MORPHOLOGICAL, AND  
MOVEMENT SCIENCES DEPARTMENT FOR THE  
APPROVATION OF STUDIES AND CLINICAL  
EXPERIMENTATION**

**TO THE ETHICAL COMMITTEE**

I, the undersigned, **Dr. Massimo Venturelli**

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**REQUEST**

**the ethical opinion about the study/experimentation**

**“EFFECTS AND COUNTERMEASURES ASSOCIATED TO BED REST IN THE  
ELDERLY”**

**1) STRUCTURE OF THE DEPARTMENT CARRYING OUT THE STUDY:**

- **Section of Movement Sciences**
- **“Mons. Arrigo Mazzali Foundation”, Mantova**

The undersigned guarantees:

- The competence and adequacy of the personnel;
- The eligibility and conformity of the available instrumentation to the current laws

**2) NAME AND SURNAME OF THE SCIENTIFIC COORDINATOR OF THE EXPERIMENTATION AND OF THOSE AUTHORIZED**

Scientific Manager: Prof. Federico Schena

Researcher: Dr. Massimo Venturelli

Health Director of Mons. Mazzali Onlus Foundation: Dr. Renato Bottura

Medical Doctors: Dr. Renato Scarsini; Dr. Ettore Muti; Dr. Andrea Storti; Dr. Giampaolo Moretti.

### 3) STUDY BACKGROUND

Bed rest has historically been used as a therapy for the control of several chronic diseases having a high incidence in the elderly population (7, 14, 19). It is also a common step in the process of physical activity reduction leading up to death. Bed rest, induced by both intrinsic and extrinsic factors related to ageing, has catastrophic effects on health, triggering a series of comorbidities that aggravate the physical decline of the elderly (5, 13, 16, 17). The harmful consequences of immobility affect the musculoskeletal, cardiopulmonary, and neurological systems, causing muscular atrophy, hypotension, thrombosis, vascular dysfunction and decubitus ulcers (5, 14, 15, 17).

For example, Paul Rousseau (14) described how the complications of bed rest trigger a spiral of events that, starting with immobility, causes a multi-organ deconditioning followed by a further worsening of the disability that originally caused bed rest. Other studies reported how immobility causes a decrease in cardiac output, heart rate, plasma volume, and a reduction in all parameters of pulmonary function (ventilation, tidal volume, maximum ventilatory capacity), leading to a reduced arterial oxygen saturation. Other consequences of bed rest are a reduction in resting metabolism and appetite besides a negative nitrogen balance.

Bed rest in the elderly is associated to a series of dysfunctions affecting the cardiovascular system, central and peripheric haemodynamic. Blood stasis in the large capacitance vessels, together with a reduced blood flow, are cofactors in the elevated risk of having venous thromboembolism (VTE) and decubitus ulcers (5). In order to diminish some of the negative effects of bed rest, passive mobilization of the patient is nowadays a consolidated practice (14), but several studies reported greater improvements in the vascular functionality of chronically immobilized patients caused by spinal cord injury and/or stroke after being treated with Functional Electrical Stimulation (FES) (3, 6, 9, 12). This type of therapeutic approach has been shown to be effective, incrementing the femoral artery diameter, improving resting blood flow and increasing flow mediated vasodilation (FMD) with no particular contraindication or low treatment tolerance being reported in past studies. Moreover, the application of FES had an evident physiological effect on blood flow that was also accompanied by a significant reduction in decubitus ulcers (18) and other complications linked to immobilization (20).

With a different approach, some studies have also verified how specific interventions may prevent and/or reduce immobilization-induced vascular dysfunctions in the bed resting elderly population. The use of anti-decubitus mattresses, the correct positioning and passive physical therapies, have all been successfully utilized in the prevention of decubitus ulcers. The

use of supports that allow a semi-recumbent position and the elastic compression of the lower limbs are effective therapies to reduce the probability of getting VTE and reduce the pooling of blood in the lower extremities (14).

Other studies (1, 2, 11, 12) have also shown how electrostimulation may be an effective intervention in the cure and prevention of the dysfunctions associated to bed rest. Broderick and colleagues (2) demonstrated that electrostimulation of the calf muscle improves venous return and prevents blood stasis in the legs during 4 hours of forced immobilization. Furthermore, bed rest studies that simulate space microgravity proved that electrostimulation is an effective method to prevent the physiological consequences of immobilization (4).

At present, no study has shown if electrostimulation can diminish the negative effects of bed rest in the vascular functions. For this reason, the objective of this study will be to verify if electrostimulation can improve and/or reduce the negative effects of immobility on the vascular functions of the lower limbs in the bed resting elderly.

## **METHODS**

Inclusion criteria: bed rest and walking inability for at least 6 months and no more than 2 years, age > 70 years.

Exclusion criteria: considering the type of intervention and the evaluations that will be performed, we will not include subjects presenting:

- Myocardial infarction (in the last 6 months)
- Symptomatic aortic stenosis
- Acute pulmonary embolism or pulmonary infarction
- Acute non-cardiac pathology that may be aggravated by electrostimulation (i.e. infection, renal insufficiency)
- Left coronary stenosis or equivalent
- Abnormal electrolytes blood concentration
- Atrial fibrillation with uncontrolled ventricular rate
- Cardiac pacemaker and/or defibrillator
- Use of anticoagulant drugs
- Stroke with consequent hemiparesis

The specialized geriatric medical team of the “Fondazione Mazzali di Mantova” will select 20 non-self-sufficient elders (age > 70 years), living temporarily in the nursing home of the foundation. The family members and/or legal caregivers of the residents will receive detailed information about the measurements and the purpose of the study. All the subjects will receive

an electrostimulation treatment on one of the lower limbs, while the contralateral one will only be evaluated but will not receive any treatment, acting as a control.

All the researchers and health care personnel participating in the study declared that they do not present any conflict of interest in the practice of their functions.

All the subjects will be evaluated through tests in order to determine:

- Anthropometric measures of the limbs
- Vascular functionality of the lower limbs through Echo Color Doppler with the Flow Mediated Dilation (FMD) technique with the objective to measure the residual vasodilatory capacity.
- The measurements will be repeated after an 8 months treatment, based on 30 minutes of electrostimulation, 5 days per week.
- The electrostimulation treatment will take place at the subject bed place for a duration of 30 minutes. The stimulation will be carried out with a professional stimulator (Genesy 1200 pro, Globus Italia Treviso). The electrodes will be placed in a balanced manner following the guidelines delineated by Maffiuletti et al. (12) on the lower right or left limb. As outlined in previous studies (2, 10-12), the intensity and the characteristics of the electric current used for the treatment (capillarization programme Genesy 1200 pro, Globus Italia) will be modulated based upon the subject tolerance.
- Treatment suspension criteria: the treatment will be suspended in case it is not tolerated by the patient, and/or it causes an altered psychophysical state that diminishes the residual quality of life.

## **STATISTICAL PROCEDURES**

A two-way ANOVA for repeated measures will be used to establish differences between groups and limbs. A Bonferroni post-hoc test will be used, when appropriate, to determine group differences.

Mantova, 14/06/2016, The applicant

A handwritten signature in black ink, appearing to read "Venturoli Marini".

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