Evaluation of the clinical effects of supplementation with probiotic supplement Proxian® in frail elderly patients treated with Enteral Nutrition (NE), IntegPro project

STUDY ID:

DATE:

REGISTRATION NUMBER:

PATIENT INITIALS:

Dear Sir / Madam (Support Administrator / Legal Guardian),

our Institute intends to conduct a clinical study and we need the collaboration of patients who, like you (your protected / assisted), possess the characteristics necessary for the study that we will illustrate.

Before you (your protected / assisted) decide on the possible participation, it is important that you understand the purpose for which the research is carried out and what it may entail for you (your protected / assisted) an eventual participation in terms of benefits, risks and inconveniences.

Please read this document carefully and, if you wish, discuss it with your family, your physician and/or ask us for clarification if the information provided is not understandable or needs further clarification.

Why is the study conducted and what does it intend to demonstrate?

Scientific research has shown that the composition of the microbiota of older subjects undergoes important variations that are significantly associated with the decline in the functionality of the immune system (immuno-senescence) and with low-grade inflammation (inflamaging). Among the various causes of this variation, there is also artificial nutrition. The most recent research suggests that probiotics, by acting on intestinal permeability, could help reduce inflammation and some of the most frequent infections among the geriatric population.

The purpose of the study is to evaluate the effect of supplementation of probiotic supplements on inflammation, infections and nutritional status in the population of older patients treated with Home Enteral Nutrition (HEN). To this end, the patients will be divided into two groups; a group to which the supplement will be administered daily for 60 days and a control group to which the placebo will be administered.

Is my participation (of my protected / assisted) mandatory?

The decision to participate in the study is free and depends only on you (your protégé / client).

If you decide to participate, you will be asked to sign the informed consent. If you agree to participate in the study, your rights will be protected according to the ethical principles established in the Helsinki Declaration and its amendments for the duration of the study.

What happens if I decide to refuse or to withdraw from the studio?

You refusal will in no way affect the quality of the services that you receive from this center. Similarly, if after having consented to participate you (your protégé / assisted) decide to withdraw from the study, you can do so freely by informing the staff of the O.U. Clinical Nutrition, without need to provide any justification and without affecting the usual quality of health services that you receive in this center.

What will my participation (of my protected / assisted) in the study involve?

If you decide to participate in the study, all the data collected will be used for scientific purposes. Participation does not involve any type of cost, but it can represent an important contribution to the improvement of knowledge which is necessary to improve the quality of life of patients in NED. The study will involve patients treated with HEN by our service who decide to participate in this study, for a period of two months from the time of enrollment or until the time of withdrawal from the study.

What risks does my participation (of my protected / assisted) in the study bring?

The Proxian supplement is generally well tolerated and there are no known cases of overdose or adverse reactions. In the event that you (your protected / assisted) should suffer damage due to participation in this trial, you are covered by an INRCA insurance policy (RCTO policy, contract number 1913058 expiring on 31/12/2019) .

What investigations (my protégé / client) will I be subjected to during the study?

40 NED subjects who meet the criteria for participation in the study will be selected.

Enrolled subjects will continue to receive all healthcare and routine medications as normally prescribed by their physician.

In addition, patients will receive a probiotic supplement for two months. The patients and / or caregivers responsible for the administration will be monitored by telephone contact that the hospital researcher will carry out in order to verify adherence to the supplementation program, to check the occurrence of any complications related to the intake of the product.

There are also free blood samples (PCR and lymphocytes), at the time of enrollment, 45 and 90 days from enrollment.

Will the information collected be confidential?

If you (your protected / assisted) decide to participate in the study, all the data collected will be electronically archived in a strictly anonymous manner, pursuant to art. 7 and art. 13 of Legislative Decree no. 196/03 in force since 1st January 2004 on the protection of individuals with respect to the processing of personal data.

All the study data can be inspected by the regulatory authorities, by the staff responsible for monitoring and verifying the procedures, without however being able to trace your identity (of your protected / assisted). The results of the study will be used for scientific purposes and will be published, but your identity (of your protected / assisted) will always remain secret. You (your protected / assisted) will also have the right to request the correction of any errors.

Will I be able to know the results of the study?

If you (your protected / assisted) wish, the results can be communicated to you at the end of the study.

Who should I contact if I need more information or help?

At any time you can ask for more information regarding the study, by contacting the responsible physician, MR. Paolo Orlandoni, telephone 071/800 3653 at this facility.

The protocol of the illustrated research project has been drawn up in accordance with the European Union Standards of Good Clinical Practice and the current revision of the Helsinki Declaration, and has been approved by the Bioethics Committee of this Institute.

If during the study or after its conclusion you wish to discuss your participation in this clinical study with someone who is not directly involved or, on the contrary, if you wish to continue participating, or to report any event you deem appropriate, you can contact the Bioethics Committee of this Institute.

You will receive a copy of this document, signed and dated.

WRITTEN INFORMED CONSENT FORM

TITLE OF THE STUDY:

Evaluation of the clinical effects of supplementation with probiotic supplement Proxian® in frail elderly patients treated with Enteral Nutrition (NE), IntegPro project

STUDY ID:

_____

DOCUMENT DATE:

_____

CENTER N.:

_____

REGISTRATION NUMBER:

_____

PATIENT INITIALS:

_____

SURNAME AND NAME OF PHYSICIAN:

_____

I, the undersigned (name and surname)

_____

Age _____ sex M F date of birth ___ / ___ / _____.

Address: Via / Piazza _____ n. _____

Postcode _____ City _____ tel.

_____

I declare as it follows:

• I will participate voluntarily in the study *Evaluation of the clinical effects of supplementation with probiotic supplement Proxian in frail elderly patients in Home Enteral Nutrition (NED), IntegPro project*,

• I have received from the aforementioned doctor all the clear and exhaustive information on the purposes and procedures of the study in which I have been asked (to my tutor / client) to take part;

• I read and understood the information sheet which was delivered to me sufficiently in advance and which confirms what I was verbally told;

• I had the opportunity to ask clarifying questions and have had satisfactory answers, as well as having had the opportunity to inform me about the details of the study with a person I trust;

• I was informed of the possible benefits that I could derive (my protégé / client could derive) and the reasonably foreseeable risks or inconvenience, and that I have had sufficient time to decide;

• I am aware:

- that participation in the study is voluntary and that I can withdraw (my protected / assisted can withdraw) from the study of my (his) spontaneous will without providing justifications, having received the certainty that both the refusal to participate in the study and my eventual withdrawal will not affect receiving the most suitable therapy for me;

- that my (of my protected / assisted) clinical data may be examined or used for scientific publications but will remain strictly confidential in compliance with current legislation and subsequent amendments and additions;

- that my (of my assisted / protected) clinical dossier may be examined, but will remain strictly confidential and that the data will be used throughout the study for the preparation of a final report intended for the Health Authorities or for a publication, whatever the outcome of the study, always

respecting the confidentiality of my identity (art. 13 of Legislative Decree no. 196/03 in force since 1 January 2004);

- that the Ethics Committee of this Institute, of which I have received the address, approved the experimental research protocol;

- that I have to sign (me or my protégé) two identical forms of this informed consent: a

original will be kept by the Physician (and kept for at least 15 years) and the second will be delivered to me;

- that for any problem or for any further information I will have to contact:

MD. ORLANDONI PAOLO

Address: Via della Montagnola 81, 60120 Ancona

telephone 071/800 36 53;

Therefore I freely consent to the participation (of my protected / assisted) in the clinical study.

The signature on this form will not affect my legal rights (of my protected / assisted).

Subject:

Name and surname:

Date …… ..

Signature……

Family member / Legal Guardian / Patient Support Administrator:

Name and surname:

Role:……..

Date …… ..

Signature……

Investigators:

Name and surname:

Date …… ..

Signature……

Witness**:

Name and surname:

Date …… ..

Signature……

** Required only if the patient or his legally recognized representative is unable to read (Ministerial Decree no. 162 of 15 July 1997 art. 4.8.9).