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Evaluation of the clinical effects of supplementation with probiotic supplement Proxian® in frail elderly patients treated with enteral nutrition

Submission date
07/07/2020

Recruitment status
No longer recruiting

Registration date
09/07/2020

Overall study status
Completed

Last Edited
27/01/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Enteral feeding refers to intake of food via the gastrointestinal (GI) tract. The GI tract is composed of the mouth, esophagus, stomach, and intestines. Enteral feeding may mean nutrition taken through the mouth or through a tube that goes directly to the stomach or small intestine.
The main aim of the study is to evaluate the effects of probiotic supplement Proxian® on infections and inflammation in frail elderly patients treated with enteral nutrition. The secondary objectives of the study are to evaluate the effects of the administration of Proxian® food supplement on the nutritional status and intestinal motility and to assess the compliance of caregivers of HEN patients and their perception of the product in different stages of administration (before and after).

Who can participate?
Patients older than 65 years treated with HEN for at least 1 month at INRCA service, who didn't assume the antibiotic therapy for at least 1 month before the enrollment, without diagnosis of pancreatitis and/or hypersensitivity to any ingredient contained in Proxian®, who didn't use any probiotic supplement in the period of 30 days previous to the enrollment and didn't participate in any clinical trial in 3 months previous to the invitation to participate in the study, whose CRP hs value is lower than 10 mg / dL, who will give their written informed consent (for patients with a serious cognitive impairment the informed consent signed by legal administrator) and whose caregiver is willing to participate.

What does the study involve?
The study will run for 90 days after the enrolment (signing the free consent). The Proxian® probiotic supplement will be administered to the intervention group for 60 days. The placebo (maltodextrin) will be administered to the control group for the same duration. The follow up will be performed for both groups 30 days after the end of administration. CRP values will be measured at enrolment, 45 days and 90 days. Information on clinical manifestations of infections

and antibiotic therapy will be gathered from caregivers on regular basis. Patients are free to decide about their participation and to withdraw from the study at any time.

What are the possible benefits and risks of participating?
There are no risks of participating in the study.

Where is the study run from?
IRCCS Istituto Nazionale Ricovero e Cura per Anziani (Italy)

When is the study starting and how long is it expected to run for?
April 2018 to September 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Paolo Orlandoni
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Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CE INRCA 18015

Study information

Scientific Title
May the use of probiotic supplements in older patients treated with enteral nutrition reduce infections and inflammation?

Acronym
INTEGPro

Study objectives
Supplementation with Proxian® probiotic supplement in frail elderly patients treated with Enteral Nutrition (EN) reduces clinical infections and inflammation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/09/2018, Ethics board of IRCCS INRCA (Via della Montagnola 81, 60129 Ancona, Italy; +39 (0)718003500; comitatoetico@inrca.it), ref: CE INRCA 18015

Study design
Randomized double-blind two-arm single-centre pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Clinical infections and inflammation in older subjects treated with home enteral nutrition

Interventions
A total of 32 subjects will be randomly assigned to the intervention group (16) or to controls (16). The Proxian® probiotic supplement will be administered to the intervention group for 60 days. Proxian® is a food supplement (Errekappa spa patent) containing encapsulated and gastro-protected probiotic micro-organisms. A Proxian® stick contains the following doses of probiotic microorganisms: Bifidobacterium lactis (DSM 23032) ≥ 1 billion cells / dose, Lactobacillus plantarum LP01 (LMG P-21021) ≥ 1 billion cells / dose and Lactobacillus buchneri Lb26 (DSM 16341) tindalized, naturally rich in selenium (20 mg). Both bifido bacteria and lactobacilli (in particular Lactobacillus plantarum) have proven to be very effective in reducing intestinal permeability (22). Being Lactobacillus buchneri Lb26 naturally rich in Selenium, Proxian® also guarantees a better bio-availability of this mineral which, together with Zinc, also contained in the Proxian® supplement, contributes to the protection of cells from oxidative stress and to the normal functioning of the immune system.
The placebo (maltodextrin) will be administered to the control group for the same duration.

The packaging of the two products - Proxian and placebo - will be identical and will be identifiable through a special code that neither the patients or caregivers responsible for the administration or researcher will know. The intervention group will be administered, through the enteral probe, 1 sachet / day of Proxian® dissolved in water. The administration will be carried out by formal and / or informal caregivers (carers and family members) who deal with the management of the patient and will be carried out 1 hour after the administration of the enteral formula. To ensure correct administration of the product, all caregivers will be specifically trained and they will be given the written instructions concerning the method of administration of the product. The caregivers will also be instructed on how to recognize and note the progress of the alvo and eventual adverse effects due to the administration of the product. In order to ensure the adherence of the participants to the project, telephone contacts on daily bases will be made with the caregivers.

Intervention Type
Supplement

Primary outcome measure
1. The onset of infections observed by detection of clinical manifestations of infections (prevalence) and antibiotic therapy (prevalence) during the period of administration and 90 days after the enrollment (30 days after the last administration)
2. The inflammation is assessed by C Reactive Protein (CRP) values in the intervention group and in controls following the administration of products (Proxian® and placebo) and lab analyses will be performed at baseline, 45 and 90 days after the enrollment

Secondary outcome measures

1. Nutritional status is assessed by Body Mass Index values assessed at baseline, 45 and 90 days after the enrollment
2. Motility is assessed by the evidence on bowel function and its variations as reported by caregivers on the occasion of each phone contact with caregivers
3. Compliance of caregivers and their perception of the product in different stages of administration (before and after) are assessed by specific questionnaires administered at the enrollment and after 60 days of administration

Overall study start date
01/04/2018

Completion date
30/09/2019

Eligibility

Key inclusion criteria
1. Age over 65 years
2. Patient treated with HEN for at least 1 month
3. No antibiotic therapy for at least 1 month before the enrollment
4. Written informed consent; for patients with a serious cognitive impairment the informed consent signed by legal administrator
5. Availability of a caregiver (formal or informal)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
32 subjects (16 intervention group, 16 controls)

Total final enrolment
43

Key exclusion criteria
1. Diagnosis of pancreatitis
2. Known hypersensitivity to any ingredient contained in Proxian®
3. Participation in other clinical trials in 3 months previous to the invitation to participate in the study
4. Use of probiotic supplements in the period of 30 days previous to the enrollment
5. CRP hs> 10 mg / dL

Date of first enrolment
02/10/2018

Date of final enrolment
15/06/2019

Locations

Countries of recruitment
Italy

Study participating centre
IRCCS Istituto Nazionale Ricovero e Cura per Anziani
Via della Montagnola 81
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/04tfzc498

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded. ERREKAPPA Spa. provided free samples of Proxian® and placebo.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
Dataset generated and analyzed during the current study will be available upon request which is to be addressed to MD Paolo Orlandoni, Clinical Nutrition, IRCCS INRCA Ancona, Via della Montagnola 81, 60127 Ancona, Italy (p.orlandoni@inrca.it; 0039/(0)71/8003653). Data will be available only after the publication of study results in a high-impact peer- reviewed journal. Data may be requested for the involvement of participants in studies on larger samples relatively to the efficacy of probiotics in similar populations. The request must be formulated by scientific contact/responsible of the study to MD Paolo Orlandoni. Data will be shared only after the acceptance of participants or legal representatives.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			07/08/2020	No	Yes
Protocol file	version V2	03/09/2018	07/08/2020	No	No
Results article	results	27/01/2021	27/01/2021	Yes	No