Information form for the participation of clinical study

AN IN VIVO PILOT STUDY ON PERMANENCE IN SALIVA OF TWO DIFFERENT PROBIOTICS STRAIN ADMINISTERED THROUGH CHEWING GUMS

Clinical study aimed at assessed the kinetic of sugar-free chewing gum on release probiotics in saliva.

We would like to propose that you participate in this research. You have the right to be informed about the purpose, characteristics and manner of the study so that you can make an informed and free decision whether or not to consent to participate in it. Please read the following carefully: the researchers involved in this project are available to answer your questions.

Data Controller	
University of Milan	(rettore@unimi.it)
Data Protection Officer	
Data Protection Officer of University of Milan	(dpo@unimi.it)
Professor or researcher scientific referent of the study	
(Maria Grazia Cagetti)	(maria.cagetti@unimi.it)

Professor or researcher scientific referent of the study

The aim of the present study is to evaluate the ability of sugar-free chewing gum, added with probiotics, to release the probiotic itself into saliva, following a single administration. The probiotics tested are species that have beneficial effects on gingivitis and halitosis and whose effectiveness has already been scientifically proven. The present research aims to evaluate the release kinetics and saliva residence times of probiotics as data on these important aspects are lacking in the literature. No side effects have been recorded so far attributable to the probiotic therapy in the present study.

Come si svolgerà lo studio?

The study includes an initial visit to verify your eligibility for participation. During the first visit, oral hygiene of the mouth, salivary flow stimulated by chewing a paraffin tablet will be evaluated and personal and anamnestic data on his general and oral health will be collected. The visit and interview will last about 15 minutes in total. During the visit, an inspection of the oral cavity and an examination will be performed to assess the amount of saliva produced.

If you agree to participate, you will be asked to show up in the morning, 2 hours after breakfast and tooth brushing and to chew a chewing gum containing one of the probiotic strains to be tested for 10 minutes. The saliva produced will be collected at predetermined time intervals over a period of about 2 hours.

This procedure will be repeated about a week apart, using chewing gum containing a different probiotic strain for a total of 3 sessions.

What does the tested product contain?	Basic ingredients	Nutritional information per 100 g

Chewing gum	Sweeteners: sorbitol, isomalt, maltitol syrup, aspartame, acesulfame K, sucralose; gum base, flavourings, stabiliser: glycerol, maltodextrin, thickeners: gum arabic, E466; colorant: E133; emulsifiers: lecithins (SOY), E473; Glazing agent: carnauba wax, antioxidant: E321. Samples may contain traces of maltodextrin and E551 (silicon dioxide).	Energy: 652 kJ / 157 kcal – Fat: 0 g (of which saturated fatty acids: 0 g) – Carbohydrates: 65 g (of which sugars: 0 g – polyols: 65 g) – Protein: 0 g – Salt: 0 g.

3 different chewing gums containing the same basic ingredients will be tested; In addition, each chewing gum will contain one of the following probiotic strains:

- *Lactobacillus rhamnosus* GG in free form (containing maltodextrin, coconut oil, pea protein, polysorbate);
- *Lactobacillus rhamnosus* GG in microencapsulated form;
- *Weizmannia coagulans* SNZ1969;

Is it mandatory to participate in the study?

Your participation in the study is completely free and on a voluntary basis as well as free of charge. In addition, if at any time you change your mind, you are free to withdraw your consent to participate without having to provide any reason.

In the event of withdrawal, the data previously acquired will still be used.

What are the steps required for your participation in the study?

Participation in the study takes place after detailed information on the characteristics, risks and benefits of the same. At the end of the information phase, you can consent to participate in the study by signing the informed consent form.

What are the possible benefits of the study?

The probiotics tested in this study have been shown to be effective on oral health, although there is no evidence on benefits after a single administration.

What are the possible risks and discomforts that could occur during the study?

There are no known risks associated with the use of the products administered during the study if applied in accordance with the manufacturer's instructions and all individual ingredients are already used in commercially used food products.

What will happen if information about your health emerges during the study?

If potentially useful information for your health emerges from the study, you can express your choice to be informed or not, in the "Expression of informed consent" section.

How will your personal data be used?

All information relating to the processing of personal data (including special categories of data) is contained in the specific information drawn up pursuant to article 13 del Reg. 2016/679 (GDPR) issued together with this information sheet.

Other important information

We inform you that this study has been approved by the Ethics Committee of the University of Milan.

The original of the informed consent expressed in writing, which will be signed by you if necessary, will be kept by the Responsible of the present study, while you are entitled to receive a copy.

During the study, you may contact the study manager for any information.

Thank you for your availability and help

STATEMENT FROM THE STUDY MANAGER

I declare that I have provided the participant with complete information and detailed explanations about the nature, purposes, procedures and duration of this research study.

I also declare that I have provided the participant with the information sheet.

SIGNATURE OF THE STUDY MANAGER Data

(MARIA GRAZIA CAGETTI)

PARTICIPANT'S INFORMATION SIGNATURE

I declare that I have received information that has allowed me to understand the research project, also in the light of the further clarifications I requested. I confirm that I have been given a copy of this information document.

SIGNATURE Data

ESPRESSIONE DI CONSENSO INFORMATO

Io sottoscritto/a

- Nome: _____ Cognome_____

- Dichiaro di aver ricevuto spiegazioni esaurienti in merito alla richiesta di partecipazione allo studio sperimentale in oggetto e sufficienti informazioni riguardo ai rischi e ai benefici implicati nello studio, secondo quanto riportato nel foglio informativo in allegato.
- Dichiaro di aver potuto discutere tali spiegazioni, di aver potuto porre tutte le domande che ho ritenuto necessarie e di aver ricevuto in merito risposte soddisfacenti.
- Sono stato inoltre informato del diritto di poter ritirare il consenso per la partecipazione alla sperimentazione in qualsiasi momento.

Pertanto, alla luce delle informazioni chemci sono state fornite (selezionare l'opzione prescelta):

Io sottoscritto/a ……

☐	ACCONSENTO	☐	NON ACCONSENTO	Alla partecipazione allo studio
☐	VOGLIO	☐	NON VOGLIO	essere informata/o su eventuali risultati utili alla mia salute derivanti dallo studio stesso *(se pertinente).* Nel caso desideri essere informata/o, indicare un contatto telefonico:

LUOGO DATA FIRMA DEL PARTECIPANTE

LUOGO DATA FIRMA DEL RESPONSABILE DELLO STUDIO