Effects of Lentinula edodes bar on lipid and antioxidant profiles in borderline high cholesterol individuals: A double blind randomized clinical trial

NCT 04186780

September 26th, 2018

WICF - Written Informed Consent Form

Clinical Study with Hypercholesterolemic Participants

You are being invited to participate as a research volunteer "**Effects of *Lentinula edodes* bar on lipid and antioxidant profiles in borderline high cholesterol individuals: A double blind randomized clinical trial".** Your participation is not mandatory and you may at any time give up and withdraw your consent. Your refusal will not harm your relationship with the researcher or the institution. You will receive an original copy of this term that contains the phone number and address of the responsible researcher and research team, and you can answer questions about the project and its participation.

RESEARCH TITLE: Effects of *Lentinula edodes* bar on lipid and antioxidant profiles in borderline high cholesterol individuals: A double blind randomized clinical trial.

RESPONSIBLE RESEARCHER: Sara Rosicler Vieira Spim, RA 50598, RG18598373 and CPF 109859368-51.

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OBJECT: This study aims to evaluate the effects of daily intake of functional food with Shiitake in patients with hypercholesterolemia for a period of 66 days.

STUDY PROCEDURES: Your participation in this research will consist of presenting at the University of Sorocaba (time, day and place) for blood collection and receiving an unidentified brown envelope with functional cereal food with Shiitake for ingestion for 33 days. After 33 days present for new blood collection and receive functional cereal food with Shiitake for another 33 days. Participants will be instructed on cereal food bars intake as to quantity (according to each participant's weight), frequency and times.

You will also be informed about the components used in the formulation of this cereal bar (Shiitake, oats, peanuts, prunes, Brazil nuts, quinoa, flaxseeds, chia, sugars and soy lecithin) so that any food intolerance, allergies regarding to the substances used. They will also be instructed to record any occurrences they find important during the study.

They will be advised regarding blood collection on the three dates for the triglyceride, total cholesterol, LDL-cholesterol, HDL-cholesterol and glucose biochemical tests at baseline, after 33 days and after 66 days. Blood collection procedures will be performed by nursing professionals at the University facilities. Blood samples will be kept refrigerated and sent to the Sorocaba Toxicological Analysis Laboratory for serum and plasma separation and freezing at - 80 °C for further analysis.

RISKS AND DISORDERS: You will be selected using simple randomization with group draw. Your participation is not mandatory, and at any time you may withdraw your participation and consent. Your refusal, withdrawal of consent will not cause harm. Participants may not be using immunosuppressive drugs or antibiotics to avoid any interaction. Women should not be pregnant, lactating or on hormone replacement to avoid any risk or injury.

BENEFITS: In addition to the benefit of eating a nutritious and functional food for sixty six days, participants will receive the results and will be able to follow the progress of the project.

COST / REFUND TO PARTICIPANT: Participation is not remunerated nor will it incur expenses for participants, any participation expenses (ticket, for example) may be paid or reimbursed by the research.

RESEARCH CONFIDENTIALITY: The data obtained through this research will be confidential and will not be disclosed on an individual level to ensure the confidentiality of your participation. The responsible researcher will undertake to make public in the

academic and scientific circles the results obtained in a consolidated manner without any identification of the participants.

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Principal Researcher
Sara Rosicler Vieira Spim

Informed Consent in Human Subjects Research

I,_____RG/SSN_____, declare that I have read the information contained in the Informed Consent Form of the project entitled **"Effects of Lentinula edodes bar on lipid and antioxidant profiles in borderline high cholesterol individuals: A double blind randomized clinical trial",** whose main researcher is Sara Rosicler Vieira Spim and as advisor Dr. Denise Grotto. Responsible nurses **Paula Monticelli Bertoni** and **Miriam Sanches do Nascimento Silveira** and Degree student **Ana Maria Holtz Pistila**. I was duly informed of the procedures that will be used, risks and discomforts, benefits, cost / reimbursement of participants, confidentiality of the research and I agree to participate.

I was also assured that I can withdraw consent at any time without incurring any discipline.

I further declare that I received a copy of the Consent Form.

Sorocaba,____,_____2018.

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Participant Name Signature