Emergency and Acceptance Department,

Anaesthesia and Critical Areas

Company Policlinico Umberto I of Rome

Information Sheet

Title of study:	IS THE PERIOPERATIVE CHANGE OF THE INSPIRATORY DIAPHRAGMATIC AMPLITUDE EVALUATED WITH ULTRASOUND TECHNIQUE PREDICTIVE OF POSTOPERATIVE ATELECTASIS? PROSPECTIVE OBSERVATIONAL STUDY IN OBESE PATIENTS UNDERGOING BARIATRIC SURGERY.
Code / Protocol Number:	
EudraCT Number:	
Promoter	
Main experimenter:	Dr. Francesco Alessandri
Address:	Emergency and Acceptance Department, Anaesthesia and Critical Areas, Azienda Policlinico Umberto I di Roma, Viale del Policlinico 155, 00161 Roma

Dear Madam/Egregious Sir,
This document provides you with all the information about the proposed study, which we want you to fully understand before you give your consent.
We are asking you to participate in an experimental clinical trial because you are suffering from pathological obesity and therefore a candidate for bariatric laparoscopic surgery. Feel free to ask any questions to the person who is informing you and, if you wish, discuss them with your family, friends or family doctor.

What is the purpose of the study?
The objective of the study is to assess in the obese patient, during gastrectomy sleeve and gastric mini-bypass surgery, whether the peri-operative change in diaphragmatic amplitude during inspiration measured with ultrasound can predict the phenomena of postoperative pulmonary atelectasis, thus providing a clinically useful tool to stratify the need for high intensity monitoring, including admission to intensive care. This will be achieved by comparing the relationship between the diaphragmatic function indexes and the PaO2/FiO2 ratio in the pre- and post-operative stages.

What does it mean that this is an observational study?
This study is defined as observational because during treatment the investigators will analyze the data collected to obtain information useful to confirm its effectiveness. This study is defined experimental because the ultrasound evaluation of the diaphragmatic excursion as an indicator of postoperative respiratory complication has not yet been evaluated in the perioperative period. This examination does not

compromise your safety. You will therefore undergo normal clinical routine procedures/treatments regardless of your participation in this study. This study has been evaluated and approved by the Ethics Committee of the Sapienza University of this hospital and you may contact them at any time if you have any questions.

Why was I chosen?
Because you are suffering from pathological obesity and must undergo bariatric surgery laparoscopy. Moreover, thanks to this evaluation your clinical condition could be better understood.

Should I participate in the study?
You are free to choose to participate in the study. If you choose to participate, you will be given a copy of this information sheet and asked to sign an informed consent form. If you choose to participate, you will still be free to withdraw at any time, without having to provide an explanation. In any case, you will receive appropriate alternative medical care.

What are the possible benefits of participating in this study?
The information that will be collected could be useful to improve the treatment of people who, like you, suffer from morbid obesity and therefore at greater risk of developing post-operative respiratory complications. Sometimes, during the course of the study, new information about the treatment/pharmaceutical in the study becomes available. If this occurs, the principal investigator will inform you and discuss the possibility of continuing the study with you. If you decide to discontinue your participation, the principal investigator will provide you with details on how best to continue the treatment of your condition. If you decide to continue the trial, you will be asked to sign an updated informed consent form.

Pregnancy
If you are currently pregnant or breastfeeding or planning to become pregnant, you will not be able to participate in the study.

What should I do if I decide to participate in this study?
If you agree to participate in this study, we will ask you to sign the informed consent form, and we will give you a signed copy of this information sheet. With your consent, you authorize us to use the clinical data available in your medical records.
The procedure that we will perform will last approximately 20 minutes before the surgery and 20 minutes after the surgery, will not lengthen the intraoperative time and will not increase the risks of the procedure.

What is the procedure?
All patients will undergo ultrasound of the diaphragm before surgery and one hour after the procedure.

What are the possible side effects of any treatment I will receive?
The ultrasound procedure does not involve any added risk other than those due to general anesthesia which are fully explained in the ordinary consent that you will sign before undergoing surgery.

What are the alternative therapies for the treatment?
Exclusive clinical and hemogasanalytic evaluation (however applied together with the ultrasound study), carrying out the normal procedures of preparation for surgery that would be carried out in any case.

What would happen if something went wrong?
Diaphragmatic ultrasound is not an invasive examination and does not involve complications.

What will happen if the trial is discontinued?
If the practice is discontinued, there will be no consequences for you of any kind.

Will my information remain confidential?
If you agree to participate in the study, your medical records will be reviewed by the Promoter and collaborators to review the results. They may also be reviewed by other regulatory personnel to ensure that the trial is conducted regularly. You will be provided with other written information about your rights and how your personal data will be processed, and you will be asked to sign a separate form to consent to the processing of your personal data.

How will the results of the study be used?
The data collected during the study will be analyzed by a statistical reference group, drawing information useful for the research under examination. Then the results will be published in scientific journals shared by the world scientific community. If the statistical analysis carried out with the data collected will provide positive results, these results will form the basis for a larger prospective study that will confirm the results observed by us. Although prospective observational and with a small sample size, this study will be welcomed with interest by the scientific community. For this reason we believe it is worthy of publication.

Who organizes and promotes this study?
The study is promoted by the Department DAI Emergency and Acceptance, Anaesthesia and Critical Areas Department of Azienda Policlinico Umberto I in Rome. The adhesion to this study does not entail any financial burden for you, nor does it provide for any compensation.

Who to contact for more information or help?
You may contact the principal investigator for information about the trial or to report any ongoing or post-trial side effects or problems:
Name: FRENCH ALESSANDRI
U.O.C: SEAC03
Phone number: 0649978024 Mail: francesco.alessandri@uniroma1.it
The study protocol proposed to you has been prepared in accordance with the European Union's Standards of Good Clinical Practice and the current revision of the Helsinki Declaration and has been approved by the Ethics Committee responsible for this hospital, which works to ensure the protection of the rights, integrity and well-being of the subjects involved in the trials.

Should you need further clarification on your rights as a patient, please send a written request to the Secretariat of the Ethics Committee of the Sapienza University in Rome at the Policlinico Umberto I- V.le of Policlinico 155, 00161;
e-mail: comitato.etico@policlinicoumberto1.it