



**S.C. Endoscopia Digestiva**

Direttore: Dr. Arnaldo Amato

Via dell'Eremo, 9/11 – 23900 Lecco

Tel. 0341.489969

Fax. 0341.489966

e-mail: a.amato@asst-lecco.it

**INFORMED CONSENT FORM**

**v.1.0**

July 14th 2025

**Title**

**Tolerability of Sedation with Remimazolam versus Midazolam in Outpatients Undergoing Upper GI or Biliopancreatic Endoscopic Ultrasound in a Non-Anesthesiologist Setting: A Prospective Observational Study (REM-EUS Study)**

Dear Patient,

A clinical study titled as follows is scheduled at this Hospital:

**Tolerability of Sedation with Remimazolam versus Midazolam in Outpatients Undergoing Upper GI or Biliopancreatic Endoscopic Ultrasound in a Non-Anesthesiologist Setting: A Prospective Observational Study (REM-EUS Study)**

The study sponsor is ASST Lecco.

---

• **What is the purpose of the study?**

The aim is to evaluate whether sedation with Remimazolam—a benzodiazepine with a safety profile demonstrated in numerous international studies—combined with Fentanyl, administered by an endoscopist physician and nursing staff, provides better patient tolerability and higher operator satisfaction compared to the routinely used sedation with Midazolam combined with Fentanyl in the context of diagnostic endoscopic ultrasound of the pancreas or upper gastrointestinal tract.

---

• **What is being asked of you?**

Participation in the study means undergoing endoscopic ultrasound as part of normal clinical practice, with the possibility of receiving sedation with either remimazolam or midazolam.

Before the procedure, your demographic and medical history data will be collected. During the procedure, your vital signs will be regularly monitored. At the end of the procedure, you will be asked to complete a questionnaire assessing your tolerance of the examination. After completing and returning the questionnaire, you may be informed of which drug was administered.



**S.C. Endoscopia Digestiva**

Direttore: Dr. Arnaldo Amato

Via dell'Eremo, 9/11 – 23900 Lecco

Tel. 0341.489969

Fax. 0341.489966

e-mail: a.amato@asst-lecco.it

---

- **Is my participation voluntary?**

Yes. You may choose whether or not to participate in this study. If you agree to participate, you will be asked to sign and date this informed consent form.

---

- **What will happen to the results of this research study?**

Your participation will contribute to scientific publication. The results of this study will be published in a scientific journal, but you will not be identified in any report or publication.

---

- **What are the benefits of participation?**

There is no guaranteed direct benefit to you. However, the data obtained will contribute to improving clinical practice in sedation management during diagnostic endoscopic ultrasound.

---

- **What are the risks of participation?**

Participation in this study does not involve additional risks beyond those associated with standard diagnostic/therapeutic procedures you are already undergoing, for which you will receive separate information from the responsible medical staff.

---

- **Ethical aspects**

The proposed research—including this consent form—has been reviewed and approved by the Ethics Committee. The study has been designed and will be conducted in accordance with national and international ethical standards for biomedical research involving human subjects, including:

- The current revisions of the Declaration of Helsinki of the World Medical Association
- Good Clinical Practice (ICH/GCP) guidelines of the European Union on clinical trials of medicinal products
- The Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention, 04/04/1997)
- Italian professional medical ethics codes and applicable national regulations on clinical studies

You may report any issue you consider relevant regarding this study to the Ethics Committee of this institution. Ethics Committee approval should not be interpreted as encouragement to participate.

---

- **Contact person**



**S.C. Endoscopia Digestiva**

Direttore: Dr. Arnaldo Amato

Via dell'Eremo, 9/11 – 23900 Lecco

Tel. 0341.489969

Fax. 0341.489966

e-mail: a.amato@asst-lecco.it

For questions regarding the study, you may contact:

Dr. Tommaso Pessarelli - Phone: 3925133075  
Study coordinator at this center

---

**DECLARATION:**

- I confirm that I have received a copy of the information sheet and informed consent form.
  - I confirm that I have read and understood this informed consent regarding the above study, that I have had sufficient time to consider the information provided, and that I have had the opportunity to ask questions.
  - I understand that my participation is voluntary and that I am free to withdraw at any time without providing any reason, and without any impact on my medical care or legal rights.
  - I therefore knowingly and voluntarily consent to participate in this study.
- 

Name and surname of the patient

---

Patient's signature and date

---

- I declare that I have discussed this informed consent with my patient and provided all necessary explanations and clarifications.
- 

Name and surname of the doctor who obtained consent

---

Signature of the doctor who obtained consent and date



**S.C. Endoscopia Digestiva**

Direttore: Dr. Arnaldo Amato

Via dell'Eremo, 9/11 – 23900 Lecco

Tel. 0341.489969

Fax. 0341.489966

e-mail: [a.amato@asst-lecco.it](mailto:a.amato@asst-lecco.it)

---

One signed copy for the patient, one signed copy for the Center.