

Scientific research process

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Randomized Controlled Trial

Randomized controlled study of the safety and efficacy of nitrous oxide-sedated endoscopic ultrasound-guided fine needle aspiration for digestive tract diseases

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1. What scientific issues does this research explore?

This research studies the application of nitrous oxide sedation in EUS-FNA, and explores the safety and effectiveness of nitrous oxide sedation.

2. How does this research complete all experimental processes?

Enrolled patients were divided randomly into an experimental group (inhalation of nitrous oxide) and a control group (inhalation of pure oxygen) and heart rate, blood oxygen saturation, blood pressure, electrocardiogram (ECG) changes, and the occurrence of complications were monitored and recorded. All patients and physicians completed satisfaction questionnaires about the examination and scored the process using a visual analog scale.

3. How does this research deal with all experimental data?

Statistical analysis was performed with the SPSS software package version 19.0 (SPSS Inc., Chicago, IL, USA). $P < 0.05$ was considered to be statistically significant.

4. How does this research deal with the pre-experiment hypotheses?

Patients were monitored closely and the following negative events were recorded: oxygen desaturation (oxygen saturation $<95\%$, but $\geq 90\%$), hypoxia (oxygen saturation $<90\%$, but $\geq 85\%$), severe hypoxemia (oxygen saturation $<85\%$), hypotension (systolic blood pressure <90 mmHg), bradycardia (heart rate <50 bpm), and tachycardia (heart rate >120 bpm). Patients and endoscopists completed questionnaires regarding their degree of satisfaction with the examination process, and scored them on a visual analog scale (VAS) scale. The following questions were included: 1) evaluation of the operation by the endoscopist: (smooth, ordinary, not smooth); 2) patient discomfort during the operation process (slight, moderate, severe); 3)

patient tolerance with the examination process (good, medium, and low); and 4) willingness to receive the same examination again if needed (yes, no).

5. What new findings does this research produce?

Nitrous oxide-sedation is a safe and effective option for patients undergoing endoscopic ultrasound-guided fine needle aspiration.