Impact of Intravenous Lidocaine on Clinical Outcomes of Patients With ARDS During COVID-19 Pandemia (LidoCovid)

ClinicalTrials.gov Identifier: NCT04609865

Recruitment Status ⓘ : Not yet recruiting
First Posted ⓘ : October 30, 2020
Last Update Posted ⓘ : November 2, 2020

See Contacts and Locations

Sponsor:
University Hospital, Strasbourg, France

Information provided by (Responsible Party):
University Hospital, Strasbourg, France

Study Description

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Brief Summary:

The purpose of our prospective monocentric, randomized, controlled trial is to evaluate the effects of intravenous lidocaine on gas exchange and inflammation in acute respiratory distress syndrome (ARDS) due or not to Covid-19 pneumonia.

Half of the patients will receive intravenous lidocaine and the other half will receive intravenous NaCl 0,9 % as placebo.

Condition or disease ⓘ	Intervention/treatment ⓘ	Phase ⓘ
Acute Respiratory Distress Syndrome (ARDS) COVID-19 Corona Virus Infection	Drug: Lidocaine 2% Drug: Control	Phase 3

Study Design

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Study Type ⓘ :	Interventional (Clinical Trial)
Estimated Enrollment ⓘ :	100 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose:	Treatment
Official Title:	Impact of Intravenous Lidocaine on Clinical Outcomes of Patients With ARDS During COVID-19 Pandemia
Estimated Study Start Date ⓘ :	November 4, 2020
Estimated Primary Completion Date ⓘ :	November 4, 2020
Estimated Study Completion Date ⓘ :	February 4, 2024

Resource links provided by the National Library of Medicine NIH NLM

Drug Information available for: Lidocaine hydrochloride Lidocaine

Genetic and Rare Diseases Information Center resources: Severe Acute Respiratory Syndrome Respiratory Distress Syndrome, Infant Acute Respiratory Distress Syndrome

U.S. FDA Resources

Arms and Interventions

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Arm ⓘ	Intervention/treatment ⓘ
Experimental: Lidocaine 2% The lidocaine infusion protocol is a bolus of 1 ml/kg (ideal weight), followed by 3mg/kg/h for the first hour, 1.5 mg/kg/h for the second hour, 0.72 mg/kg/h for the next 22 hours,and then 0.6mg/kg/h for 14 days or until extubation.	Drug: Lidocaine 2% the lidocaine infusion protocol is a bolus of 1 ml/kg (ideal weight), followed by 3mg/kg/h for the first hour, 1.5 mg/kg/h for the second hour, 0.72 mg/kg/h for the next 22 hours, and then 0.6mg/kg/h for 14 days or until extubation.
Placebo Comparator: Control The NaCl 0,9% infusion protocol is a bolus of 0.05 ml/kg (ideal weight), followed by 0.15 ml/kg/h for the first hour, 0.075 ml/kg/h for the second hour, 0,36 ml/kg/h for the next 22 hours, and then 0.03 ml/kg/h for 14 days or until extubation.	Drug: Control The NaCl 0,9% infusion protocol is a bolus of 0.05 ml/kg (ideal weight), followed by 0.15 ml/kg/h for the first hour, 0.075 ml/kg/h for the second hour, 0,36 ml/kg/h for the next 22 hours, and then 0.03 ml/kg/h for 14 days or until extubation.

Outcome Measures

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Primary Outcome Measures ⓘ

1. alveolar-capillary gas exchange after two days of treatment [Time Frame: At 48 hours after the first treatment administration]

   PaO2/FiO2 ratio

Secondary Outcome Measures ⓘ

1. alveolar-capillary gas exchange From day 0 to day 21 or until coming out of intensive care [Time Frame: From day 0 to day 21 or until coming out of intensive care]

   PaO2/FiO2 ratio : a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

2. Ventilator-free days [Time Frame: At day 28 and at day 90]

   a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

3. Measure the effects of Intravenous Lidocaine on Biomarkers : Ferritin [Time Frame: At Day 0, day 2, day 7, day 14 and at day 21]

   a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

4. Measure the effects of Intravenous Lidocaine on Biomarkers : bicarbonates [Time Frame: At Day 0, day 2, day 7, day 14 and at day 21]

   a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

5. Measure the effects of Intravenous Lidocaine on Biomarkers : CRP [Time Frame: At Day 0, day 2, day 7, day 14 and at day 21]

   a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

6. Measure the effects of Intravenous Lidocaine on Biomarkers : LDH [Time Frame: At Day 0, day 2, day 7, day 14 and at day 21]

   a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

7. Measure the effects of Intravenous Lidocaine on Biomarkers : IL-6 [Time Frame: At Day 0, day 2, day 7, day 14 and at day 21]

   a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

8. Measure the effects of Intravenous Lidocaine on Biomarkers : Tropo HS [Time Frame: At Day 0, day 2, day 7, day 14 and at day 21]

   a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

9. Measure the effects of Intravenous Lidocaine on Biomarkers : Triglycerides [Time Frame: At Day 0, day 2, day 7, day 14 and at day 21]

   a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

10. Measure the effects of Intravenous Lidocaine on Biomarkers : CBC with lymphocytes count [Time Frame: At Day 0, day 2, day 7, day 14 and at day 21]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

11. Antithrombotic activity of Intravenous Lidocaine on platelets [Time Frame: At Day 0, day 2, day 7, day 14 and at day 21]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

12. Antithrombotic activity of Intravenous Lidocaine on ACT ratio [Time Frame: At Day 0, day 2, day 7, day 14 and at day 21]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

13. Antithrombotic activity of Intravenous Lidocaine on fibrinogen [Time Frame: At Day 0, day 2, day 7, day 14 and at day 21]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

14. Antithrombotic activity of Intravenous Lidocaine on D-Dimers [Time Frame: At Day 0, day 2, day 7, day 14 and at day 21]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

15. Antithrombotic activity of Intravenous Lidocaine on TEG [Time Frame: At Day 0, day 2, day 7, day 14 and at day 21]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

16. Antithrombotic activity of Intravenous Lidocaine on thromboembolic events [Time Frame: At Day 0, day 2, day 7, day 14 and at day 21]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

17. Plasma concentration of albumin and Lidocaine [Time Frame: 4 hours after first administration, at day 2, day 7, day 14 and at day 21]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

18. Search for hemodynamic dysfunction: Blood pressure measurement in mmHg [Time Frame: daily from day one to day 14]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

    Blood pressure in mmHg will be measured

19. Search for hemodynamic dysfunction: Cardiac frequency in beats per minute will be assessed [Time Frame: daily from day one to day 14]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

    Cardiac frequency in beats per minute will be assessed

20. Search for hemodynamic dysfunction: Sinus rythm will be assessed [Time Frame: daily from day one to day 14]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

    Sinus rythm will be assessed

21. Search for hemodynamic dysfunction: Vasopressors and inotropes drugs use will be reported [Time Frame: daily from day one to day 14]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

    Vasopressors and inotropes drugs use will be reported

22. Search for hemodynamic dysfunction: EKG : PR, QRS, QTc intervals in ms will be measured [Time Frame: daily from day one to day 14]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

    EKG : PR, QRS, QTc intervals in ms will be measured

23. ICU ileus: laxation response [Time Frame: daily from Day 0 to Day 28]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

24. Opioids, sedative and curare sparing effect (drugs dosage) [Time Frame: daily from Day 0 to Day 28]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

25. Evaluate the impact of Lidocaine IV on ICU outcomes : re-intubation [Time Frame: From Day0 to Day28 and at Day90]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

26. Evaluate the impact of Lidocaine IV on ICU outcomes : ICU length of stay [Time Frame: From Day0 to Day28 and at Day90]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

27. Evaluate the impact of Lidocaine IV on ICU outcomes : ICU complications [Time Frame: From Day0 to Day28 and at Day90]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

28. Cough at extubation time or in the 24 hours after extubation or weaning from respiratory support (in case of tracheostomy) [Time Frame: extubation day]

    a comparison will be made between Lidocaine and control groups in patients with acute respiratory distress syndrome (ARDS) due to Covid-19 and in patients with ARDS without Covid-19.

Eligibility Criteria

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Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Age ≥18 years
- Hospitalized in ICU
- Presence of all of the following conditions, within one week of a clinical insult or new or worsening respiratory symptoms:
- PaO2/FiO2 ≤300 mmHg with positive end-expiratory pressure (PEEP) ≥5 cmH2O
- Bilateral opacities not fully explained by cardiac failure or fluid overload
- Intubated and sedated for mechanical protective ventilation
- Affiliation to the French Sociale security
- Beta HCG negative for women

For Covid-19 subgroup:

- Covid-19 infection (RT-PCR < 7 days and/or another approved diagnostic technique and/or typical CT appearance of COVID-19 pneumonia

Exclusion Criteria:

- Allergy to amide local anesthetics
- Acute porphyria
- Disorders of atrioventricular conduction requiring a non-done permanent electrosystolic pacing
- Uncontrolled epilepsy
- Fluvoxamine treatment
- Class III antiarrhythmic agent treatments (amiodarone, dronedarone)
- Class I antiarrhythmic agent (quinidine, diisopyramide, hydroquinidine, flecainid, propafenone)
- Hepatocellular insufficiency defined by PT<15% in the absence of anti-vitamin K
- Patient under a tutelage measure or placed under judicial protection
- Known pregnancy
- Breastfeeding

Contacts and Locations

Go to

Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

*Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCT04609865***

Contacts

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Sponsors and Collaborators

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More Information

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Responsible Party:	University Hospital, Strasbourg, France
ClinicalTrials.gov Identifier:	NCT04609865 History of Changes
Other Study ID Numbers:	7820
First Posted:	October 30, 2020 Key Record Dates
Last Update Posted:	November 2, 2020
Last Verified:	October 2020

Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No

Additional relevant MeSH terms:

- Coronavirus Infections
- Severe Acute Respiratory Syndrome
- Respiratory Distress Syndrome, Newborn
- Respiratory Distress Syndrome, Adult
- Acute Lung Injury
- Lung Diseases
- Respiratory Tract Diseases
- Respiration Disorders
- Infant, Premature, Diseases
- Infant, Newborn, Diseases
- Virus Diseases
- Lung Injury
- Coronaviridae Infections
- Nidovirales Infections
- RNA Virus Infections
- Respiratory Tract Infections
- Lidocaine
- Anesthetics, Local
- Anesthetics
- Central Nervous System Depressants
- Physiological Effects of Drugs
- Sensory System Agents
- Peripheral Nervous System Agents
- Anti-Arrhythmia Agents
- Voltage-Gated Sodium Channel Blockers
- Sodium Channel Blockers
- Membrane Transport Modulators
- Molecular Mechanisms of Pharmacological Action