

Long-Term Oxygen Therapy for 24 or 15 Hours per Day in Severe Hypoxemia | New England Journal of Medicine

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Abstract

Background

Long-term oxygen supplementation for at least 15 hours per day prolongs survival among patients with severe hypoxemia. On the basis of a nonrandomized comparison, long-term oxygen therapy has been recommended to be used for 24 hours per day, a more burdensome regimen.

Methods

To test the hypothesis that long-term oxygen therapy used for 24 hours per day does not result in a lower risk of hospitalization or death at 1 year than therapy for 15 hours per day, we conducted a multicenter, registry-based, randomized, controlled trial involving patients who were starting oxygen therapy for chronic, severe hypoxemia at rest. The patients were randomly assigned to receive long-term oxygen therapy for 24 or 15 hours per day. The primary outcome, assessed in a time-to-event analysis, was a composite of hospitalization or death from any cause within 1 year. Secondary outcomes included the individual components of the primary outcome assessed at 3 and 12 months.

THE NEW ENGLAND JOURNAL OF MEDICINE

Daily Duration of Oxygen Therapy for Severe Hypoxemia

A PLAIN LANGUAGE SUMMARY

Based on the NEJM publication: Long-Term Oxygen Therapy for 24 or 15 Hours per Day in Severe Hypoxemia by M. Ekström et al. (published September 10, 2024)


Chronic severe hypoxemia, or low oxygen levels in the blood, can affect people with chronic obstructive pulmonary disease (COPD) and other respiratory conditions and is associated with poor survival. Long-term oxygen therapy improves survival but is burdensome, and the daily duration of supplemental oxygen needed to improve survival is not known.

In this trial, researchers assessed hospitalization and mortality among patients with chronic severe hypoxemia who received long-term oxygen therapy for either 24 or 15 hours per day.

WHY WAS THE TRIAL DONE?
Data from nonrandomized comparisons have suggested that survival might be better with long-term oxygen therapy used for 24 hours per day than with the typically recommended 15 hours per day. Data from randomized trials directly comparing these two durations of oxygen therapy are lacking.


HOW WAS THE TRIAL CONDUCTED?
241 adults who were starting oxygen therapy for chronic severe hypoxemia at rest were randomly assigned to receive long-term oxygen therapy (LTOT) for either 24 or 15 hours per day. The primary outcome was a composite of hospitalization or death from any cause within 1 year.

LTOT 24 Hr/Day



117 Patients

LTOT 15 Hr/Day



124 Patients

PATIENTS

WHO: 241 adults
Mean age, 76 years
Women: 59%; Men: 41%

CLINICAL STATUS: Chronic severe hypoxemia at rest
Primary diagnoses: COPD in 71%; pulmonary fibrosis in 14%

TRIAL DESIGN

- PHASE 4
- MULTICENTER
- REGISTRY-BASED
- RANDOMIZED
- CONTROLLED
- LOCATION: 20 RESPIRATORY OUTPATIENT CLINICS IN SWEDEN

RESULTS

At 1 year, the rate of hospitalization or death from any cause did not differ significantly between the two treatment groups.

Hospitalization or Death from Any Cause at 1 Year

Group	Rate (per 100 Person-Yr)
LTOT 24 Hr/Day	124.7
LTOT 15 Hr/Day	124.5

Any Adverse Event

Group	Number of Events
LTOT 24 Hr/Day	8
LTOT 15 Hr/Day	9

The number of adverse events, including burn injuries, fall-related injuries, and nosebleeds, was similar in the two groups.

ADHERENCE

At 12 months, patients reported closely adhering to their assigned daily duration of treatment.

LINKS: FULL ARTICLE | NEJM QUICK TAKE | EDITORIAL

FURTHER INFORMATION

Trial registration: ClinicalTrials.gov number, NCT03441204
 Trial funding: Crafoord Foundation and others
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Results

Between May 18, 2018, and April 4, 2022, a total of 241 patients were randomly assigned to receive long-term oxygen therapy for 24 hours per day (117 patients) or 15 hours per day (124 patients). No patient was lost to follow-up. At 12 months, the median patient-reported daily duration of oxygen therapy was 24.0 hours (interquartile range, 21.0 to 24.0) in the 24-hour group and 15.0 hours (interquartile range, 15.0 to 16.0) in the 15-hour group. The risk of hospitalization or death within 1 year in the 24-hour group was not lower than that in the 15-hour group (mean rate, 124.7 and 124.5 events per 100 person-years, respectively; hazard ratio, 0.99; 95% confidence interval [CI], 0.72 to 1.36; 90% CI, 0.76 to 1.29; $P=0.007$ for nonsuperiority). The groups did not differ substantially in the incidence of hospitalization for any cause, death from any cause, or adverse events.

Conclusions

Among patients with severe hypoxemia, long-term oxygen therapy used for 24 hours per day did not result in a lower risk of hospitalization or death within 1 year than therapy for 15 hours per day. (Funded by the Crafoord Foundation and others; REDOX ClinicalTrials.gov number, [NCT03441204](https://www.clinicaltrials.gov/ct2/show/study/NCT03441204).)