BOX SUBSTUDY

CLINICAL TRIAL SUMMARY

Presenters	Jesper Kjaergaard
Objectives	To evaluate mortality rates in resuscitated comatose out-of-hospital cardiac arrest patients with and without diabetes

https://clinicaltrials.gov/study/NCT03141099

TRIAL DESIGN

Randomized, Controlled, Multi-centre Study

SAMPLE SIZE

110 patients with preexisting diabetes

INCLUSION CRITERIA

- Age ≥18 years
- Preexisting Diabetes
- Out-of-hospital cardiac arrest (OHCA) of presumed cardiac cause
- Sustained return of spontaneous circulation (ROSC)
- Unconsciousness (GCS <8) (patients not able to obey verbal commands) after sustained ROSC

METHODOLOGY

- Diabetic and non-diabetic patients from the BOX trial were compared.
- The BOX trial was a randomized, controlled, multicenter study that evaluated two mean arterial pressure targets (63 vs. 77 mm Hg) in a double-blinded design, along with two open-label interventions: liberal vs. restrictive oxygenation (9–10 vs. 13–14 kPa) and two durations of fever control (36 vs. 72 hours).
- The primary outcome of this sub-study was 365-day survival.
- Multiple logistic regression models adjusted for known outcome-related factors, including age, sex, witnessed arrest (yes/no), and time to return of spontaneous circulation (in minutes).

RESULTS

Among the 110 patients (14%) with preexisting diabetes, those with diabetes were older (median age 67 [IQR 59–73] vs. 63 [53–72]) and had more comorbidities compared to non-diabetic patients.

One-year all-cause mortality was higher in the diabetic group (45% vs. 34%, p = 0.02).

After adjusting for age, sex, witnessed arrest, and place of arrest, the logistic regression model yielded an adjusted odds ratio of 1.47 (95% CI: 0.93–2.30, p = 0.10).

No significant interactions were found between diabetes status and any of the study interventions, with p-values ranging from 0.10 to 0.80.

CONCLUSION

Preexisting diabetes was linked to higher unadjusted 365-day mortality. However, among diabetic patients with out-of-hospital cardiac arrest (OHCA), outcomes did not differ based on blood pressure targets, oxygenation levels, or durations of fever control.

Josiassen J, Møller JE, Schmidt H, et al. Diabetes in resuscitated comatose out-of-hospital cardiac arrest patients - A substudy of the randomized BOX trial. *Eur Heart J Acute Cardiovasc Care*. Published online May 13, 2025. doi:10.1093/ehjacc/zuaf073