

# The Effect of Rewarming on the Injury Outcome, Vital Sign and Arterial Blood Gases in Trauma Patients: a Randomized Controlled Trial

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## Abstract

**Background & Aims:** Trauma is a major challenge for public health. The prevalence of hypothermia in trauma patients is high and rapid recognition is important to prevent further harmful outcomes. The purpose of this study was to determine the effect of rewarming on injury outcome, injury severity, and arterial blood gases of trauma patients.

**Materials & Methods:** In this randomized clinical trial, the total sample size consisted of 96 patients with trauma referred to the emergency department of Ayatollah Mousavi Hospital in Zanjan (n= 50 in control group and n= 46 in intervention group). After approval of the study and approval of the Ethics Committee (code: ZUMS.REC.1396.163), patients were randomly divided into intervention and control groups (received routine care) after applying entry and exit criteria. The intervention is in the form of the temperature-control package that includes several rewarming strategies as full coverage of the trauma patient with a hat, blanket and warmed intravenous fluids (between 38 and 41 ° C). The primary outcome measure included demographic and clinical characteristics, vital signs, and arterial blood gas and the change from the baseline at the end of the procedure. These parameters were recorded every 15 minutes for the first hour, then 6 hours later until the patient was transferred from the emergency department. The outcome (survived, dead) after rewarming in trauma patients was determined.

**Results:** Data analysis showed that the mean temperature of the intervention and control group before intervention was  $36/04 \pm 0/26$  and  $36/04 \pm 0/31$ , respectively, which was not statistically significant ( $p = 0/250$ ). The mean of the mean temperature of the intervention and control group six hours after the intervention was  $36/83 \pm 0/26$  and  $36/53 \pm 0/26$ , respectively, which was statistically significant ( $p < 0/001$ ). Considering the measurement of physiological parameters (HR, SBP, and RR) at intervals determined by repeated measures methods, the results were statistically significant and the trend in the intervention group showed a better result. The severity of anatomical injury (ISS) in the intervention group was lower than the control group ( $p = 0/040$ ). Two groups of intervention and control in terms of parameters of arterial blood gases (pH, PaCO<sub>2</sub> and BE) before intervention ( $p = 0/097$ ) compared to intervention after 6 hours ( $p = 0/093$ ) and 12 hours ( $p = 0/421$ ) were different. There were no statistically significant differences between the two groups, but before the intervention, significant differences were observed between PaO<sub>2</sub> and SaO<sub>2</sub> ( $p = 0/005$ ).

**Conclusion:** The two modes of temperature protection equally maintained body temperature in trauma patients during uncomplicated hospitalization. The evidence from our study suggests that rewarming can be effective in creating balance in some arterial blood gases and physiological parameters in the trauma patient. However, this issue should be separately investigated in further studies.

**Keywords:** Hypothermia, Rewarming, Trauma, Mortality

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## Introduction

Trauma is a major challenge for public health and the mortality and disability-related to it are increasing worldwide (1, 2). The World Health Organization (WHO) plays an important role in reducing this challenge. Based on WHO information in 2018, more than 3400 people die on the world's roads every day and tens of millions of people are injured or disabled every year (3). According to statistics provided by the secretary of the scientific committee in the Iranian association of surgeons, trauma is the third leading cause of death in Iran after cancer and heart disease (4, 5). Improving the quality of trauma patient care is a nursing challenge that reduces mortality (6).. Trauma patient care involves a six-phase interconnected chain including pre-hospital resuscitation, hospital resuscitation, ultimate care, surgery, critical care, and rehabilitation (6, 7). Most of the trauma patients suffer from a disorder such as hypothermia (8). Hypothermia is a condition that lowers the body's central temperature to less than 35 degrees Celsius that leads to peripheral vascular contraction lactate accumulation in the blood, acidosis, and ultimately interruption in the patient's coagulation system. The prevalence of hypothermia-related to trauma varies from 1.6% to 66% in Norway(9) and this index in Iran has been reported in more than 40% of patients referred to curative educational centers (10-12). The prevalence of hypothermia and mortality related to it increases with the severity of the injury and also with a higher injury severity score (ISS) (13). Considering the nature of the trauma and the unpredictability of hypothermia in injured patients, it is important to follow the proper therapeutic technique such as rewarming (14). The process of returning body temperature to the normal body temperature is called rewarming (15). In people with hypothermia, the decision to use inactive or

active rewarming techniques should be based on clinical parameters and hypothermia levels (16). In most hospitals, emergency medical personnel have limited knowledge of the management of accidental hypothermia such as Damage Control Resuscitation and its associated reduction in bleeding and its associated complications have been noted, while mortality following trauma or hypothermia is higher and is the third leading cause of death. As a result, the choice of rewarming treatment in accidental hypothermic patients is based on the fragmented knowledge of the individual physician. On the other hand, when looking for answers in the literature, we found no randomized controlled trial that would cover the topic in detail. This randomized controlled trial was initiated to obtain more precise data on the effect of rewarming on injury outcome, injury severity, and arterial blood gases of trauma patients hospitalized in the emergency department of Zanjan Ayatollah Mousavi hospital.

## Materials and Methods

### Setting and trial design:

In this randomized controlled trial, the rewarming approach was carried out by the researcher (S.S.M.) from 1<sup>st</sup> of December, 2017, to March 31<sup>st</sup>, 2017. The study population consisted of 154 trauma patients admitted to the emergency center of Ayatollah Mousavi Hospital in Zanjan city (located in the North West of Iran). The study started after the approval of the Zanjan University's Research Ethics Committee (code: ZUMS.REC.1396.163). At the start of the study, the researcher obtained written consent from the patient or his / her guardian and provided them the information about the purpose and conditions of the study.

### Sample size:

This sample size is estimated according to the standard formula and parameters from a similar study (15).

$$[n = \frac{(1.96+1.28)^2 \times (.5^2 + .3^2)}{(36.2-35.9)^2} \cong 40]$$

The average body temperature before rewarming is 35.9 °C± 0.5, and the average body temperature after rewarming is 36.2 °C± 0.3, β=90% and α=0.05.

#### **Inclusion and exclusion criteria:**

The inclusion criteria for selecting the trauma patients were as follows: aged 18-65 years, the central body temperature between 28 and 38 °C, without loss of consciousness, and those transferred to the center in less than one hour.

Exclusion criteria included: departing from the center earlier than 6 hours, death within less than 24 hours after admission to the emergency center, disagreement of the patient or her custody to participate in the study.

#### **Randomization:**

A random allocation method using a random number table was utilized, which is the best method of planning in randomized clinical trial studies. All patients were randomly assigned to study. If the random number which was chosen in the random number table was paired, the trauma patient was placed in the intervention group and if the odd number appeared, the trauma patient was placed in the control group. By this method, determining the type of group for the next patient was completely randomized.

#### **Intervention:**

In the present study, the control group received routine care of the trauma and the intervention group received the rewarming as an intervention. The intervention is in the form of a temperature-control

package that includes several rewarming strategies as described below and the temperature recording for the trauma patient in the first hour of admission in the emergency department (every 15 minutes) and 6 hours later until the normal temperature is reached for the intervention group. For the control group, routine care and installation of a patient-side temperature maintenance instruction booklet were also considered.

#### **Intervention:**

The rewarming strategies included the following items:

- Installing an educational panel as a care intervention, including controlling and recording the body temperature of the body by the tympanic thermometer and taking actions to maintain the body's temperature and prevent its loss along the patient's bed.
- Remove the wet and bloody clothes and cover the patient's body with dry clothes.
- Maintain room temperature in the range of 25-20 ° C.
- Full coverage of the head, body, and legs of the patient with a hat, blanket, etc.
- Maintain the temperature of injection fluids between 38 and 41 ° C and liquids that can adjust the temperature between 36 and 43 ° C such as Liquids calibrated called Bigger Mark.

#### **Measurements:**

Measuring the variables of research in two groups (intervention/control) was as follows:

- Measure and record the body temperature with the same and calibrated tympanic thermometer when the patient is admitted to the emergency department.

- Repeat measuring the central temperature of the patients in the two groups during the first hour (every 15 minutes) and then 6 hours later.
- Registration of data related to ABG at the time of admission to the emergency department and repeat it at 6 and 12 hours from admission time for both intervention and control groups.
- Registration of the total length of admission to the emergency center, intensive care unit and hospital for both intervention and control groups.
- Registration of mortality (with admission date) after 24 hours to 10 days for both intervention and control groups.

Data collected from the form included patient demographic information (age, sex) and trauma-related factors including (trauma anatomy locations, initial central body temperature, and trauma mechanism, mode of delivery, fluid therapy in the field, etc.) and related data. It was the result of injury and arterial blood gases. All measurements were performed by the researcher herself. To assess the validity, a questionnaire was sent to 10 experts and necessary changes were made based on their suggestions.

All Vital Signs Measuring Equipment(German Mark Tympanic Beurer's Thermometer Digital Ft58 - Marked Zenith 7002 ZTH Standby Barometer and 1800 S Bliss Vital Signs Monitor), Blood Heaters and Fluid Marks Biegler Model 585 BW Turning between 41 and 37 degrees Celsius (with manual adjustment of 2.8 degrees Celsius) and the Medica Arterial Blood Gas Analyzer, Ayatollah Mousavi Hospital Unit, prior to commencement of coordination with the Medical

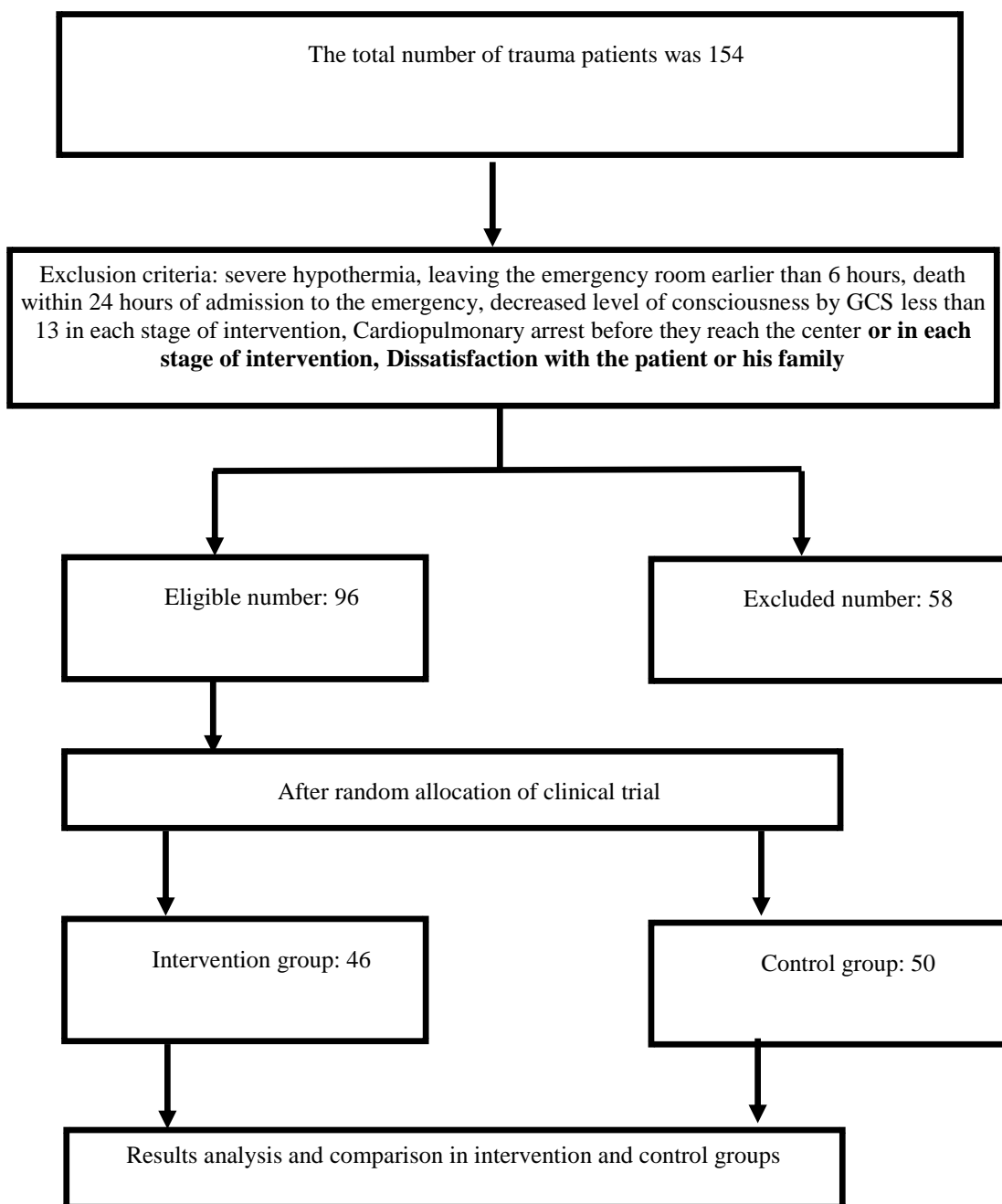
Equipment Unit approved by the University of California Medical Sciences Relevant documents were collected. All costs of research, including the cost of calibration and experiments, are borne by the researcher.

#### **Statistical analysis:**

Statistical analyses were conducted using IBM SPSS Statistics for Windows, version 22(IBM Corp., Armonk, NY, USA). For demographic data and traumatic factors, when the variable was quantitative, most descriptive indicators such as mean and standard deviation were reported, and in the case of qualitative variables, frequency and percentage were often reported. All data were analyzed by the standard statistical tests (Independent T-test, ANOVA, or equivalent in non-parametric interventions, logistic regression and Repeated Measures to compare measurements of vital signs and arterial blood gases at different time points) using SPSS software Version 22. The significance level was considered 0.05.

#### **Results**

From the beginning of December to the end of March 2017, 154 trauma patients were referred to the emergency center of Ayatollah Mousavi Hospital in Zanjan province, Iran. Of them, 96 eligible trauma patients were selected and randomly assigned to intervention and control groups. 50 (52.1%) patients were assigned to the intervention group and 46 (47.9%) of them were randomly assigned to the control group. Figure 1 shows the flow diagram of the present RCT study at each stage.



**Figure (1).** Flow diagram showing enrollment and randomization of this randomized controlled trial.

Table 1 showed the demographic and clinical characteristics of the study groups. Most of the patients in both groups were male (72% versus 28%,  $p=492$ ) and the mean age of the patient in the intervention group in comparison to the control group was higher ( $p=0.004$ ). The mean of the waiting time to reach the Emergency

center and admission duration of trauma patients was higher in the control group in comparison to the intervention group, but this difference was not statistically significant ( $p>0.05$  for both). The vehicle accident, fall, and violence were the major causes of trauma in both groups.

**Table (1):** Demographic and clinical characteristics of the study groups.

Variables	Subgroups	Control group (n = 50)	Intervention group (n = 46)	p-value
Gender, N (%)	Male	37(74)	33(71.7)	0.492
	Female	13(26.0)	13(28.3)	
Age (mean $\pm$ SD)		38.52 $\pm$ 11.87	45.61 $\pm$ 11.92	0.004
*Waiting for time 1, (mean $\pm$ SD)		13 $\pm$ 15	17 $\pm$ 21	0.357
**Waiting for time 2, (mean $\pm$ SD)		25 $\pm$ 31	21 $\pm$ 24	0.543
***Admission duration, (mean $\pm$ SD)		16 $\pm$ 4	15 $\pm$ 4	0.538
ISS		18.92 $\pm$ 7.45	15.91 $\pm$ 6.49	0.030
Rewarming		31(62) Active external rewarming 19(38) active and passive external rewarming	46(100) passive external rewarming and non-invasive core rewarming	
Transfer to the emergency center, N (%)	Emergency	40(80)	42(91.3)	0.291
	Medical System			
Trauma cause, N (%)	Personal vehicle Accident	10(20)	4(8.7)	0.069
	Fall	23(46.0)	31(67.4)	
	Violence	15(30.0)	12(26.1)	
	Electric shocks	8(16.0)	0(0.0)	
	Cutting	2(4.0)	1(2.2)	
	Tissue crunching	1(2.0)	1(2.2)	
		1(2.0)	0(0.0)	

\*Waiting time 1: Waiting time at the accident place by minutes.  
\*\*Waiting time 2: Waiting time to reach the Emergency center by minutes.  
\*\*\*Admission duration of traumatic patients by hours.

Table 2 also indicates that no statistically significant differences were observed between both intervention and control groups in the emergency center of Ayatollah Mousavi's hospital, Zanjan, with regard to vital signs such as heart rate, blood pressure, and respiratory rate

before the intervention and after the intervention and also after 2 days from intervention ( $p > 0.05$  for all). However, the central body temperature at all times of intervention was statistically significant between the two mentioned groups ( $p < 0.05$ ).

**Table (2):** Distribution of mean differences in vital signs for patients under study who were referred to the emergency center of Ayatollah Mousavi Hospital in Zanjan, in Arrival time, intervention time until 2 days from intervention.

Groups	Vital signs			
	*CBT	**HR	***BP	****RR
Arrival time	-	-	-	-
Intervention	36.01 $\pm$ 0.26	92.50 $\pm$ 11	94.50 $\pm$ 17	21.59 $\pm$ 4
Control	36.04 $\pm$ 0.31	92.40 $\pm$ 10	94.50 $\pm$ 17	23.40 $\pm$ 4
<sup>a</sup> p-value	0.149	0.499	0.096	0.138
15 minutes later	-	-	-	-
Intervention	36.17 $\pm$ 0.28	91.39 $\pm$ 85	95.80 $\pm$ 16	22.50 $\pm$ 4
Control	36.09 $\pm$ 0.31	91.38 $\pm$ 80	95.80 $\pm$ 16	22.98 $\pm$ 4
<sup>a</sup> p-value	0.023	0.919	0.056	0.490
30 minutes later	-	-	-	-
Intervention	36.16 $\pm$ 0.25	90.78 $\pm$ 14	99.90 $\pm$ 13	22.49 $\pm$ 5
Control	35.11 $\pm$ 0.21	90.78 $\pm$ 14	90.78 $\pm$ 14	21.52 $\pm$ 4

<sup>a</sup> p-value		0.437	0.485	0.874
	0.017			
45minutes later	-	-	-	-
Intervention	36.41±0.21	89.28±11	101.70±11	22.81±5
Control	36.28±0.22	89.23±13	101.70±11	20.88±4
<sup>a</sup> p-value	0.003	0.578	0.524	0.352
60 minutes later	-	-	-	-
Intervention	36.54±0.22	80.70±10	103.60±11	21.24±3
Control	36.41±0.24	80±7	103.60±11	20.38±2
<sup>a</sup> p-value	0.004	0.455	0.058	0.322
6 hours later	-	-	-	-
Intervention	36.83±0.26	86.53±83	108.90±12	20.48±3
Control	36.53±0.26	86±50±81	108.90±12	20.63±3
<sup>a</sup> p-value	0.001	0.966	0.066	0.212
2 days later	-	-	-	-
Intervention	37.20±0.31	81.05±75	115.44±18	11.29±8
Control	37.28±0.23	81.05±75	115.44±28	13.63±7
<sup>a</sup> p-value	0.474	0.612	0.429	
Total	<sup>b</sup> p-value in Intervention	P=0.001	P=0.015	P=0.002
	<sup>b</sup> p-value in Control	P<0.001	P<0.001	P=0.006

\* CBT: Core Body Temperature  
 \*\*HR: Heart Rate  
 \*\*\* BP: Blood Pressure  
 \*\*\*\* RR: Respiratory Rate  
<sup>a</sup> p-value: calculated mean difference from a t-test.  
<sup>b</sup> p-value: calculated mean difference in three times from repeated measure test

The results of logistic regression in Table 3 indicate that the chance of death occurring after rewarming in the intervention group compared to the control group is 0.62. This low risk is not statistically significant and the

rewarming operation does not reduce the chance of mortality in trauma patients in the intervention group or control groups.

**Table (3):** Outcome(survived, dead) after rewarming in trauma patients referred to the emergency department of Ayatollah Mousavi hospital in Zanjan

Outcome	Groups		Odds ratio	95% CI
	Intervention(n=46)	Control(n=50)		
Survived	43	48	0.62	0.05-6.7
Dead	3	2		

Table 4 shows the effect of rewarming on the distribution of arterial blood gas mean for patients who were referred to the emergency center of Ayatollah Mousavi Hospital in Zanjan (Before the intervention, 6 hours later and 12 hours later). There were significant differences between between PaO<sub>2</sub> and SaO<sub>2</sub> arterial blood gas in the intervention and control groups before

intervention (p<0.005). After the rewarming operation, these arterial blood gases along with PaCO<sub>2</sub>, BE and PH in both group, will be received in a constant and balanced state for these types of gases and there were no significant differences between intervention and control group (p>0.05 for all).

**Table (4):** Distribution of arterial blood gas mean for patients who were referred to the emergency department of Ayatollah Mousavi Hospital in Zanjan

Time	Arterial blood gas (mmHg)					
	Groups	PH	PaO2	PaCo2	SaO2	BE
Before intervention	Intervention	7.4±0.07	68.06±6	32.79±9.5	91.79±1.9	-2.57±15
	Control	7.3±0.1	64.34±6	35.08±8.1	89.44±7.8	-5.27±4.9
	<sup>a</sup> p-value	0.099	0.005	0.208	0.005	0.519
6 hours later	Intervention	7.4±0.07	72.51±11	35.16±6.6	93.38±2.3	-4.58±5
	Control	7.4±0.06	72.22±8.6	35.73±8.5	92.90±2.3	-2.91±5
	<sup>a</sup> p-value	0.095	0.513	0.719	0.495	0.106
12hours later	Intervention	7.4±0.08	82.33±19	35.11±8.2	94.65±2.6	-3.02±5.4
	Control	7.2±1.2	82.45±17	33.21±10	95±2.8	-2±4.85
	<sup>a</sup> p-value	0.062	0.791	0.376	0.583	0.393
Total	<sup>b</sup> p-value in	0.127	0.011	0.409	0.612	0.329
	Intervention					
	<sup>b</sup> p-value in Control	0.393	0.140	0.475	0.540	0.609

<sup>a</sup> p-value: calculated mean difference from a t-test.  
<sup>b</sup> p-value: calculated mean difference in three times from repeated measure test.

## Discussion

Hypothermia has been reported in most studies as an independent risk factor for mortality in patients with trauma (17, 18). As the incidence of hypothermia is high at the time of EMS arrival (9). The recommendation of the researchers in this study is that, based on the significant statistical and clinical evidence in this randomized controlled trial, measurement and monitoring of body temperature should be performed in all patients with trauma.

The result in Table 2 indicated that there is no statistically significant difference in the aspect of vital signs for patients referred to the emergency center of Ayatollah Mousavi Hospital in Zanjan, in Arrival time, intervention time until 2 days from intervention, except for the central body temperature. The previous clinical trial conducted by Lundgren et al. demonstrated that there were significant differences in vital signs (such as heart rate and respiratory rate) of trauma patients who received the active warming strategy as an intervention in comparison to those who did not receive the active warming strategy.

Our findings in this study (Table 3) showed that the rewarming operation did not change the clinical and

statistical significance in reducing the mortality rate of trauma patients in the intervention or control group. This finding was in line with the Beilman et al.. They reported that hypothermia did not increase the risk of death (16% of death in hypothermia versus 12% death in non-hypothermia patients,  $p = 2826$ )(18). In contrast, Konstantinidis et al. reported that maintaining central body temperature in patients with brain trauma and hypothermia can be effective in reducing their mortality (19). Perhaps small sample size is one of the reasons for this observed inconsistency between our study and the study conducted by Konstantinidis et al. However, clinically, many researchers in human studies have reported the relationship between severity of injury and degree of hypothermia and have stated that a person with traumatic shock and vibration and hypothermia has reduced oxygen transmission and, consequently, this patient has a higher risk for death and other unpleasant outcome caused by hypothermia.

Our finding in Table 4 shows the effect of rewarming on the distribution of arterial blood gas mean for patients understudy who were referred to the emergency center of Ayatollah Mousavi Hospital in Zanjan (Before the intervention, 6 hours later and 12 hours later). There



were significant differences between PaO<sub>2</sub> and SaO<sub>2</sub> arterial blood gas in the intervention and control groups before intervention ( $p < 0.005$ ). After doing the rewarming operation, these arterial blood gas along with PaCO<sub>2</sub>, BE and PH in both group, will be received in a constant and balanced state for these types of gases and there is no significant difference in this view between intervention and control group ( $p > 0.05$  for all). Our findings were consistent with previous literature which has reported that the passing of the time, temperature changes, the duration of storage of the blood sample and its storage temperature were effective factors in the results of arterial blood tests (20). Researchers in this study also agree that if we do not want the results of the experiments in this direction to change, the analysis of these gases should be carried out as soon as possible after the sampling.

Collaborating with pre-hospital providers is essential to prevent accidental hypothermia and reduce the impact of adverse outcomes. Future studies in this regard are suggested to use a dedicated team trained in rewarming strategy for traumatic hypothermia patients and conducting multicenter studies in different geographical locations.

The results of this study will lead to the clinical training of nurses in the field of thermal care; setting up a systematic and accurate trauma patient information system; improving the quality of services by implementing quality control programs and implementing preventive programs for secondary injuries in pre-hospital care.

The present study has multiple limitations. First, according to the conditions of the trauma patient at an early stage, sufficient information from the history of the patient's health (as a confounding variable) is not available. Second, due to the necessity of performing paraclinical tests such as CT scan, etc., it was not possible to carry out continuous temperature care in intra-hospital transfers. This factor increased the time

duration needed to reach the normal central temperature in the trauma patient and disrupted the control of researchers on the condition of the study. Third, according to defined exclusion criteria for research and confounding factors such as the severity of injury and loss of consciousness in head trauma could not show a causal relationship between hypothermia and mortality.

## Conclusion

In summary, our study showed that both methods were effective in preventing hypothermia and maintaining body temperature, but in the intervention group, the patients had appropriate oxygenation and tissue perfusion status, which is an important factor in the correction of metabolic acidosis in Trauma triad of death. The evidence from our study suggests that rewarming can be effective in creating balance in some arterial blood gases and physiological parameters in the trauma patient. Ultimately, the risk of death in the intervention group was lower than the control group, but the risk was not statistically significant and rewarming did not decrease the risk of death in trauma patients without hypothermia.

## Conflict of interest statement

The authors declare no conflicts of interest.

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