Study Protocol and Statistical Analysis Plan

Official Title

Acute Effects of Upper-Limb Ischemic Preconditioning on Judo-Specific Upper-Body Performance in Junior Judo Athletes: A Randomized, Sham-Controlled Crossover Trial

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Study Identification

Item	Details
Official title	Acute Effects of Upper-Limb Ischemic Preconditioning on Judo-Specific Upper-Body Performance in Junior Judo Athletes: A Randomized, Sham-Controlled Crossover Trial
Brief title	Upper-Limb Ischemic Preconditioning and Judo-Specific Performance
Study type	Interventional (randomized, sham-controlled, single-blind, two-period, two-sequence crossover trial)
Sponsor / responsible institution	Kastamonu University
Principal investigator	Bayram Ceylan, PhD, Kastamonu University
Ethics committee approval	Faculty of Physical Education and Sport Ethics Committee, 4/2026, dated 28/09/2026
Study site	Judo training hall (dojo), Karaganda National Research Buketov University named after academician Ye.A. Buketov, Karaganda, Kazakhstan

1. Background and Rationale

Judo is an Olympic combat sport characterized by intermittent high-intensity efforts in which gripping the opponent's jacket (*kumi-kata*), breaking the opponent's balance (*kuzushi*) and pulling actions (*hikidashi*) place high demands on the forearm, shoulder and back musculature. Interventions that improve upper-body grip and pulling performance or accelerate recovery are therefore of practical interest to athletes and coaches.

Ischemic preconditioning (IPC) consists of brief, repeated cycles of limb blood-flow occlusion with a pneumatic cuff followed by reperfusion. IPC has been proposed as a non-invasive, low-cost priming strategy to improve exercise performance and recovery, but findings are inconsistent and depend on the protocol, the limb occluded and the training status of the participants. In judo, IPC has mainly been applied to the lower limbs before whole-body throwing tests, with conflicting results. Because the upper limbs require lower pressures for complete arterial occlusion and show a greater local deoxygenation response than the lower limbs, upper-limb IPC may be particularly relevant for upper-body-dominant judo tasks. No sham-controlled crossover study has examined individualized bilateral upper-limb IPC on isolated, judo-specific upper-body gripping and pulling tests.

2. Objectives and Hypotheses

2.1 Primary objective

To determine whether a single bout of bilateral upper-limb IPC, compared with a sham procedure, improves judo-specific upper-body performance, assessed by the Static Judogi Grip Strength Test (SJGST), the Dynamic Judogi Grip Strength Test (DJGST) and the 20-s hikidashi uchi-komi test (Hikidashi UK test).

2.2 Secondary objectives

- To examine the acute pre-exercise systolic and diastolic blood pressure (SBP, DBP) response to IPC.
- To examine heart rate (HR) responses to and recovery from the judo-specific tests.

- To examine maximal isometric handgrip strength (HGS) before, immediately after and 30 min after the tests.
- To examine rating of perceived exertion (RPE) and perceived muscle soreness (PMS) after the tests and during recovery.

2.3 Hypothesis

Compared with the sham condition, upper-limb IPC will improve judo-specific upper-body performance and attenuate post-exercise physiological, neuromuscular and perceptual fatigue.

3. Study Design

This is a single-blind, sham-controlled, randomized, two-period, two-sequence (AB/BA) crossover trial. Each participant attends three sessions separated by 3 days: a familiarization session (Session 1) and two experimental sessions (Sessions 2 and 3), in which IPC or SHAM is applied in a randomized, counterbalanced order. The 3-day interval serves as a washout period between experimental conditions.

3.1 Randomization and allocation

Participants are allocated to one of two sequences (SHAM→IPC or IPC→SHAM) using a computer-generated random sequence prepared by a researcher not involved in testing.

3.2 Blinding

Participants are not informed of the study hypothesis or of which cuff condition is expected to be effective (single-blind). The researchers administering the interventions and tests are not blinded to the condition. To limit observer bias, all tests are scored by the same experienced evaluator using predefined criteria from video recordings.

4. Study Population

4.1 Inclusion criteria

- Male judo athletes aged 17–21 years
- Brown or black belt, with at least 5 years of judo practice
- Regular participation in official national or international competitions
- Regular judo training (approximately 6 sessions per week)
- No musculoskeletal injury in the previous 6 months

4.2 Exclusion criteria

- Cardiovascular, vascular or metabolic disease
- Resting blood pressure ≥ 140/90 mmHg
- History of deep-vein thrombosis or other thrombotic events
- Smoking
- Use of medication or dietary supplements that could affect performance

- Current weight reduction for competition

4.3 Recruitment and consent

Athletes are recruited from judo clubs in Karaganda. Written informed consent is obtained from all participants aged 18 years or older. For participants younger than 18 years, written permission is obtained from a parent or legal guardian, together with the athlete's written assent. Participation is voluntary, and participants may withdraw at any time without consequence.

4.4 Withdrawal

Participants may withdraw at any time. The investigators may also withdraw a participant for safety reasons (e.g., an adverse reaction to cuff inflation, injury or illness). The number, sequence and stage of withdrawals, and the reasons when known, are recorded and reported in the participant flow diagram.

5. Interventions

5.1 Ischemic preconditioning (IPC)

IPC is applied to both upper arms simultaneously with the participant seated, using pneumatic cuffs (9 cm width × 55 cm length; Riester, Germany) placed as proximally as possible on the upper arm. The protocol consists of three cycles of 5-min occlusion followed by 5-min reperfusion (total duration 30 min). The occlusion pressure is individualized at 50 mmHg above the participant's resting SBP measured at baseline (T1). Cuff inflation takes approximately 30 s, and occlusion time is counted from the moment the target pressure is reached.

Complete arterial occlusion is verified with a fingertip pulse oximeter (Oxywatch, ChoiceMMed, USA) placed on the index finger of each cuffed arm. Disappearance of both the pulse-rate and peripheral oxygen saturation (SpO_2) readings is taken as the onset of complete arterial occlusion, and the signal must remain absent throughout each occlusion period.

5.2 Sham (SHAM)

The sham procedure is identical in cuff placement, timing and duration, except that the cuffs are inflated to 20 mmHg, a pressure that does not restrict arterial or venous blood flow.

6. Study Procedures

6.1 Session 1 – familiarization

Height is measured with a stadiometer, and body mass, muscle mass and body fat percentage are assessed by bioelectrical impedance (BC-545, TANITA, Japan) in the morning after an overnight fast. Participants are familiarized with all performance tests, rating scales and cuff inflation.

6.2 Sessions 2 and 3 – experimental sessions

1. Resting measurements (T1): after 10 min of seated rest, SBP and DBP (left arm; automated oscillometric device, Control D, India), HR (HR10, Polar, Finland) and HGS are measured.
2. IPC or SHAM intervention (30 min).
3. Post-intervention measurements (T2): SBP, DBP and HR within 1–2 min after the end of the final reperfusion period, after cuff removal.
4. Standardized 10-min warm-up followed by passive rest.
5. Judo-specific tests in a fixed order (SJGST, DJGST, Hikidashi UK test) with 10 min of passive rest between tests.
6. Post-test measurements (T3): HR, RPE, HGS and PMS immediately after the last test.
7. Recovery measurements (T4): HR, HGS and PMS after 30 min of passive recovery.

Participants are instructed to avoid strenuous exercise and to refrain from caffeine and alcohol for 24 h before each session, and to maintain their usual diet and sleep throughout the study. Experimental sessions take place between 10:00 and 12:00 h, at the same time of day (±1 h) for each participant, 2 h after the usual breakfast, under controlled conditions (25–27 °C; 45–60% relative humidity).

Table 1 Schedule of Assessments

Assessment	Session 1	T1 (rest)	IPC / SHAM	T2 (post-intervention)	Judo tests	T3 (post-test)	T4 (30 min)
Eligibility, consent/assent	X						
Height, body composition	X						
Familiarization	X						
SBP, DBP		X		X			
Heart rate		X		X		X	X
Handgrip strength		X				X	X
Pulse oximetry (occlusion check)			X				
SJGST, DJGST, Hikidashi UK test					X		
RPE						X	
PMS (upper and lower body)						X	X
Adverse events		X	X	X	X	X	X

DBP, diastolic blood pressure; DJGST, Dynamic Judogi Grip Strength Test; IPC, ischemic preconditioning; PMS, perceived muscle soreness; RPE, rating of perceived exertion; SBP, systolic blood pressure; SJGST, Static Judogi Grip Strength Test; UK, uchi-komi.

7. Outcome Measures

7.1 Primary outcome measures

1. **Static Judogi Grip Strength Test (SJGST).** Two judogi are rolled around a horizontal bar positioned at 180 cm. The participant grips the lapels and remains suspended with

the elbows fully flexed for as long as possible. Outcome: time (s) until the elbows extend. Time frame: Sessions 2 and 3, approximately 10 min after the end of the intervention.

2. **Dynamic Judogi Grip Strength Test (DJGST).** While suspended by the judogi, the participant performs as many elbow flexion–extension repetitions as possible; a repetition is counted when the movement goes from full extension to 90° of elbow flexion, with no imposed cadence. Outcome: number of valid repetitions. Time frame: Sessions 2 and 3, approximately 21 min after the end of the intervention.
3. **20-s hikidashi uchi-komi test (Hikidashi UK test).** The participant grips the judogi of the same passive partner of similar body mass and repeatedly pulls the partner forward to break his balance, combining the pull with partial trunk rotation, without completing the throw. Outcome: number of valid repetitions in 20 s (balance clearly broken). Time frame: Sessions 2 and 3, approximately 32 min after the end of the intervention.

7.2 Secondary outcome measures

- **Systolic and diastolic blood pressure (mmHg)** at T1 and T2.
- **Heart rate (beats·min^{−1})** at T1, T2, T3 and T4.
- **Handgrip strength (kg), right and left hand**: highest of 3 maximal attempts of 3–5 s per hand (standing, elbow extended, 15 s rest between attempts), at T1, T3 and T4.
- **Rating of perceived exertion (arbitrary units)**: Borg CR-10 scale (0 = rest, 10 = maximal effort) at T3.
- **Perceived muscle soreness of the upper and lower body (arbitrary units)**: 0 (no soreness) to 10 (very intense soreness) at T3 and T4.

8. Safety

IPC with a pneumatic cuff is a widely used, non-invasive procedure in healthy athletes. Expected effects include temporary discomfort, pressure, tingling or numbness in the arm during occlusion, and transient skin redness after cuff release. Rare risks include small skin bruises (petechiae) and, very rarely, thrombotic events; individuals with cardiovascular or thrombotic risk factors are excluded. The performance tests may cause fatigue, muscle soreness and, rarely, musculoskeletal strain. Cuff inflation is stopped immediately if the participant reports severe pain or discomfort. All procedures are supervised by trained staff, and any adverse event is recorded, followed up and reported to the ethics committee as required.

9. Data Management and Confidentiality

Each participant is assigned a numeric code. Data are recorded on coded case report forms and entered into a password-protected database; the key linking codes to identities is stored separately and accessible only to the principal investigator. No names or identifying

information are included in datasets, publications or public documents. Video recordings are used only for scoring and are stored securely.

10. Ethical Considerations

The study is conducted in accordance with the Declaration of Helsinki and has been approved by the Faculty of Physical Education and Sport Ethics Committee of Karaganda National Research Buketov University named after academician Ye.A. Buketov (approval no. 4/2026). Written informed consent (participants ≥ 18 years) or parental permission with participant assent (participants < 18 years) is obtained before any study procedure. Participation is voluntary and unpaid, and withdrawal has no consequences for the athlete's training or team membership.

11. Statistical Analysis Plan

11.1 Sample size

The sample size was determined a priori in G*Power (version 3.1.9.7) for a repeated-measures ANOVA (within factors) with six measurements, corresponding to the 2 (intervention) × 3 (time) design of the HGS outcome. Assuming a large effect size ($f = 0.40$), $\alpha = .05$, power = 0.95, a correlation among repeated measures of 0.5 and a nonsphericity correction of 1, 12 participants are required ($\lambda = 23.04$; critical $F_{5,55} = 2.38$). To allow for dropouts, 14 participants are recruited. For the primary performance outcomes, which are paired comparisons between two conditions, a sensitivity analysis (matched-pairs t test) indicates that with 13 participants, $\alpha = .05$ and 80% power, the minimum detectable effect is Cohen $d = 0.85$.

11.2 Analysis population

All participants who complete both experimental sessions are included in the analysis (per-protocol, complete-case). Because the comparison is within participants, participants who withdraw before completing both conditions are excluded from the analysis and reported in the participant flow diagram. No imputation of missing data is planned.

11.3 Descriptive statistics and assumptions

Data are presented as mean (SD) with 95% confidence intervals (CIs); ordinal variables (RPE, PMS) are additionally presented as median (interquartile range). Normality is assessed with the Shapiro–Wilk test, skewness and kurtosis on the paired difference scores (IPC − SHAM) and on the residuals of the repeated-measures models.

11.4 Primary analysis

SJGST, DJGST and Hikidashi UK test performance are compared between IPC and SHAM with paired-sample t tests when difference scores are normally distributed, and with the Wilcoxon signed-rank test otherwise. Mean differences (IPC − SHAM) are calculated from the individual paired differences and reported with 95% CIs. Effect sizes are Cohen d (calculated

from the SD of the differences; 0.2 small, 0.5 medium, 0.8 large) and the matched rank-biserial correlation (r_{rb}; 0.1 small, 0.3 medium, 0.5 large).

11.5 Secondary analyses

- Two-way repeated-measures ANOVA (intervention × time) for HR (2 × 4), HGS right and left (2 × 3), and SBP and DBP (2 × 2). Sphericity is checked with Mauchly's test and the Greenhouse–Geisser correction is applied when violated. Partial eta squared (η^2_p; 0.0099 small, 0.0588 medium, 0.1379 large) is reported.
- When a significant interaction is found, simple main effects of time are examined within each intervention; when a significant main effect of time is found, Holm-corrected post hoc comparisons are performed.
- RPE and PMS are compared between interventions at each time point, and between time points within each intervention, with the Wilcoxon signed-rank test.
- Baseline adjustment: because resting values may differ between sessions, between-condition differences at T2 for SBP and DBP are additionally adjusted for baseline by regressing the IPC − SHAM difference at T2 on the IPC − SHAM difference at T1 (analysis of covariance approach for crossover data).
- Robustness check: if the residuals of the DBP or SBP models are not normally distributed, the changes from T1 to T2 are compared between interventions with the Wilcoxon signed-rank test.

11.6 Crossover-specific analyses

To check for period and carryover effects, all analyses are repeated as mixed-design ANOVAs with sequence (SHAM→IPC, IPC→SHAM) as a between-subject factor. The main effect of sequence is interpreted as a carryover effect, and the intervention × sequence interaction as a period effect.

11.7 Multiplicity

The Holm–Bonferroni procedure is applied within each family of paired comparisons (rest, post-intervention, judo-specific performance, post-test and 30 min). Unadjusted and Holm-adjusted *P* values are reported.

11.8 Significance level and software

Statistical significance is set at $P < .05$ (two-tailed). Analyses are performed with JASP (JASP Team) and G*Power (version 3.1.9.7).

12. Publication Policy

Results will be submitted to a peer-reviewed journal and reported in accordance with the CONSORT 2010 extension for randomized crossover trials, regardless of the direction of the findings. Only aggregated, de-identified data will be published.

13. Key References

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7. Marocolo M, Hohl R, Arriel RA, Mota GR. Ischemic preconditioning and exercise performance: are the psychophysiological responses underestimated? Eur J Appl Physiol. 2023;123(4):683–693.