



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/US94/04063 (22) International Filing Date: 21 April 1994 (21.04.94) (30) Priority Data: 08/055,003 30 April 1993 (30.04.93) US (71) Applicant: UNIVERSITY OF NEW MEXICO [US/US]; Al- buquerque, NM 87131 (US). (72) Inventors: MONTNER, Paul; 303 Spring Creek Place, N.E., Albuquerque, NM 87122 (US). CHICK, Thomas, W.; 2 Inwood Circle, Bay City, TX 77414 (US). STARK, Dan; 11705 Copper Place, N.E., Albuquerque, NM 87123 (US). RIEDESEL, Marvin, L.; 4612 Osuna Court, N.E., Albuquerque, NM 87109 (US). (74) Agents: GITLER, Stewart, L. et al.; Hoffman, Wasson & Gitler, Suite 522, 2361 Jefferson Davis Highway, Arlington, VA 22202 (US).</p>		<p>(81) Designated States: AU, BB, BG, BR, BY, CA, CN, CZ, FI, HU, JP, KP, KR, KZ, LK, LV, MG, MN, MW, NO, NZ, PL, PT, RO, RU, SD, SK, UA, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p>
<p>(54) Title: AN EXERCISE HYDRATION REGIMEN TO ENHANCE EXERCISE ENDURANCE AND PERFORMANCE</p>		
<p>(57) Abstract</p> <p>An exercise regimen which enhances exercise endurance and performance. The regimen includes pre-exercise hydration with a glycerol solution combined with hydration during exercise with a glycerol based solution to prolong hydration effects. The first pre-exercise glycerol solution regimen begins 2 hours prior to exercise and ends 1/2 hour before exercise begins. The hydration during exercise regimen combines glycerol with a carbohydrate and sodium to prolong fluid retention.</p>		

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**AN EXERCISE HYDRATION REGIMEN TO ENHANCE
EXERCISE ENDURANCE AND PERFORMANCE**

GOVERNMENT RIGHTS

5 This invention was made in the performance of work supported by the National Institute of Health GCRC Award #5MOIRR00997-16 through the University of New Mexico Clinical Research Center, and the U.S. Government has certain rights therein.

BACKGROUND OF THE INVENTION

10 The present invention relates to an exercise regimen which enhances exercise endurance by hydration with a glycerol solution prior to inception of exercise, combined with hydration during exercise with a glycerol and carbohydrate based solution to optimize endurance.

15 Oral replacement solutions are widely used in athletic and recreational events. Strenuous exercise as well as exposure to sunlight and heat can cause significant physiological changes. Subjects exercising or working in the heat or for prolonged periods of time are at risk for developing impaired function or heat-related injuries. In order to prevent heat-related injuries such as heat exhaustion, heat stroke and dehydration syndrome, a number of compositions and solutions have been suggested.

20 In the Runner's World article, entitled "HYPERHYDRATION" by Liz Applegate (September 1992), glycerol has been suggested as a way to preserve blood volume, moderate heart rate and allow more blood to be sent to the skin for cooling. No analysis of a particular use or regimen is discussed nor are there specifics given concerning when to use it or in what combination or proportions thereof.

30 Further, in a published study by Koenigsberg et al, entitled, "40 hour Glycerol-Induced Hyperhydration", there is some evidence that glycerol hyperhydration can be maintained for up to 40 hours with ongoing ingestion of glycerol.

35 In "Hyperhydration with glycerol solutions", authored by Riedesel et al, American Physiological Society, 1987, glycerol was studied and its affect on dilute saline solution retention as well as general fluid retention.

In "Effects of glycerol-induced hyperhydration prior to exercise in the heat on sweating and core temperature", authored by Lyons et al, Medicine and Science in Sports and Exercise, 1990, the effects of glycerol induced hyperhydration prior to exercise in the heat or sweating and core temperature was studied. Here, exercise was started 2.5 hours after the fluids were ingested. The study concluded that glycerol induced hyperhydration reduced the thermal burden of moderate exercise.

In addition, U.S. Patent No. 5,147,650, issued on September 15, 1992, found that glycerol containing solution, compared to water or Gatorade® type drink, ingested during exercise resulted in an expanded blood volume, lower heart rate, and lower rectal temperature during exercise.

The invention herein described is a novel exercise regimen for enhancing endurance and performance in activities such as hiking, soccer, football, etc. The subject exhibits an increased total body water level and therefore an improved cardiac stroke volume in the absence of fluids or even with the use of glycerol or water in a non-regimented fashion.

BRIEF SUMMARY OF THE INVENTION

The invention relates to a novel exercise regimen for ameliorating the adverse physiological effects which result from physical exertion and heat exposure. The subject hydration regimen comprises the steps of: ingesting a solution of glycerol and water prior to inception of the exercise. The subject begins ingestion of the solution, at a given rate by mouth, two hours before the inception of the exercise and stops 1/2 hour prior to inception. The subject then begins to exercise and ingests a second solution comprising glycerol, carbohydrate, sodium and water at a given rate during exercise.

Combination of a pre-exercise glycerol solution hydration regimen with a glycerol/carbohydrate/sodium solution hydration regimen during exercise results in an unique and optimal methodology for improving endurance performance.

DETAILED DESCRIPTION OF THE INVENTION

The invention described herein is a novel exercise hydration regimen which has been shown to improve physiological response in subjects. Specifically, the invention comprises an exercise hydration regimen wherein a solution of from 0.78-2.0 gms/kg of glycerol and 26 ml/kg of water are ingested by mouth starting 2 hours before and continuing up until 1/2 hour before the start of exercise. This would correspond to a 3-8% solution of glycerol, and preferably a 4.6% solution. Total volume ingested over the 1 1/2 hour hydration period is 26 ml/kg. This pre-exercise hydration regimen is then supplemented by fluid replacement during exercise. A second solution is ingested during exercise to prolong the benefit of the pre-exercise hydration. The second solution comprises from 0.4 to 1.5% glycerol, from 6-8% of a carbohydrate such as glucose and from 0-10 mEq sodium, ingested at a rate of 800-1600 ml/hr.

Glycerol hyperhydration can be maintained for up to forty hours with ongoing ingestion of glycerol. A glycerol containing solution, compared to water or glucose, results in expended blood volume, lower heart rate, and lower rectal temperature. These beneficial physiological effects improve performance.

However, gastric emptying rates are impaired by high osmolality. For example, 1/2 of a 5% solution of carbohydrate (250 mosm) would be emptied in 20 minutes while 1/2 of 12.5% solution (675 mosm) would be emptied in 45 minutes. Thus solutions containing greater than 1.5% glycerol in addition to 6% glucose significantly impair gastric emptying. A solution containing from 0.4 to 1.5% glycerol, in addition to 6-8% carbohydrate (glucose) and 0-10 mEq sodium, ingested at a rate of 800-1600 ml/hr enhance hydration during exercise and prolong performance.

The combination of pre-exercise glycerol enhanced hydration regimen and glycerol enhanced hydration regimen during exercise produces a unique and optimal exercise regimen to enhance endurance and performance.

WHAT IS CLAIMED IS:

1. An exercise hydration regimen to enhance endurance and performance of a subject comprising the steps of:
 - a) ingesting a first solution of glycerol and water at the rate of from 10 to 30 ml/kg/hr by mouth two hours before inception of exercise; and
 - b) continuing ingestion of said first solution up until 1/2 hour before the start of said exercise.
2. An exercise hydration regimen in accordance with claim 1, further comprising the step of:
 - c) ingesting a second solution of glycerol, carbohydrate, sodium and water by mouth during said exercise at the rate of from 10 to 30 ml/kg/hr.
3. An exercise hydration regimen in accordance with claim 1 wherein said first solution comprises 3-8% glycerol.
4. An exercise hydration regimen in accordance with claim 1 wherein said first solution comprises 4.6% glycerol.
5. An exercise hydration regimen in accordance with claim 2 wherein said second solution comprises from 0.4 to 1.5% glycerol, 6-8% carbohydrate and 0-10 mEq sodium.
6. An exercise hydration regimen to enhance endurance and performance of a subject comprising the steps of:
 - a) ingesting a first solution of glycerol and water at the rate of from 10 to 30 ml/kg/hr by mouth two hours before inception of exercise; and
 - b) continuing ingestion of said first solution up until 1/2 hour before the start of said exercise; and
 - c) ingesting a second solution of glycerol, carbohydrate, sodium and water by mouth during said exercise at the rate of from 10 to 30 ml/kg/hr.

7. An exercise hydration regimen in accordance with claim 6 wherein said first solution comprises 3-8% glycerol.

8. An exercise hydration regimen in accordance with claim 6 wherein said first solution comprises 4.6% glycerol.

5 9. An exercise hydration regimen in accordance with claim 6 wherein said second solution comprises from 0.4 to 1.5% glycerol, 6-8% carbohydrate and 0-10 mEq sodium.

10 10. An exercise hydration regimen to enhance endurance and performance of a subject comprising the steps of:

10 a) ingesting a first solution of glycerol and water, wherein the first solution comprises 3-8% glycerol, by mouth at the rate of from 10 to 30 ml/kg/hr, two hours before inception of exercise; and

15 b) continuing ingestion of said first solution up until 1/2 hour before the start of said exercise; and

20 c) ingesting a second solution of glycerol, carbohydrate, sodium and water, wherein said second solution comprises from 0.4 to 1.5% glycerol, 6-8% carbohydrate and 0-10 mEq sodium, by mouth during said exercise at the rate of from 10 to 30 ml/kg/hr.

11. An exercise hydration regimen in accordance with claim 10 wherein said first solution comprises 4.6% glycerol.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/04063

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61K 31/52, 31/70, 33/14, 47/00,
US CL : 424/439; 426/810; 514/23, 53, 264; 536/23, 264

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/439; 426/810; 514/23, 53, 264; 536/23, 264

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,981,687 (FREGLY ET AL) 01 January 1991, see entire document.	1-11
Y	US, A, 5,089,477 (FREGLY ET AL) 18 February 1992, see entire document.	1-11
Y	US, A, 5,147,650 (FREGLY ET AL) 15 September 1992, see entire document.	1-11
A	US, A, 3,234,089 (MCQUARRIE) 08 February 1966, see entire document.	1-11
A	US, A, 4,649,051 (GYLLANG ET AL) 10 March 1987, see entire document.	1-11

Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/04063

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,415,576 (STANKO) 15 November 1983, see entire document.	1-11
A	US, A, 4,351,835 (STANKO) 28 September 1982, see entire document.	1-11
A	US, A, 4,645,764 (STANKO) 24 February 1987, see entire document.	1-11
A	US, A, 4,874,606 (BOYLE ET AL) 17 October 1989, see entire document.	1-11
A	US, A, 4,853,237 (PRINKKILA ET AL) 01 August 1989, see entire document.	1-11
A	US, A, 4,839,347 (FRANZ) 13 June 1989, see entire document.	1-11
A	Medicine and Science in Sports and Exercise, Volume 22, No. 4, issued 1990, T. P. Lyons et al, "Effects of glycerol-induced hyperhydration prior to exercise in the heat on sweating and core temperature", pages 477-482, especially pages 477-482.	1-11
A	U. S. Army Medical Research Bulletin, issued August 1992, E. W. Askew, "Practical advice for soldiers and athletes: Hydration for top physical performance", page 3.	1-11
A	American Physiological Society, issued 1987, M. L. Riedesel et al, "Hyperhydration with glycerol solutions", pages 2262-2268, especially pages 2262-2268.	1-11
A	RUNNER'S WORLD, issued September 1992, O.A., "Hyperhydration", pages 71 -72, especially pages 71-72.	1-11