

Report Documentation Page

Form Approved
OMB No. 0704-0188

Public reporting burden for the collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to a penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.

1. REPORT DATE

11 FEB 2014

2. REPORT TYPE

Final

3. DATES COVERED

22 Feb 2011 - 11 Feb 2014

4. TITLE AND SUBTITLE

FDG20110007H Evaluation of 5 hour Energy drink on the blood pressure and electrocardiograph parameters on young healthy volunteers: A randomized, double blind, crossover, placebo-controlled trial.

5a. CONTRACT NUMBER

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Dr. Sachin Shah, Lt Col Michael Lee, Lt Col Nicholas Milazzo, Capt Anthony Dargush, Maj Carolyn Lacey

5d. PROJECT NUMBER

FDG20110007H

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Clinical Investigation Facility David Grant Medical Center 101 Bodin Circle Travis AFB, CA 94535

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

Clinical Investigation Facility David Grant Medical Center 101 Bodin Circle Travis AFB, CA 94535

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT

Approved for public release, distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

NTRODUCTION: The impact of energy drinks on the cardiac rhythm remains unknown. QT/QTc interval prolongation has been known to induce life threatening arrhythmias. We sought to determine the impact of 5-Hour Energy shot on the QTc interval after acute and chronic consumption. METHODS: This was a randomized, placebo controlled, crossover study enrolling young healthy volunteers not on any medications. Subjects received the study drink (5 Hour Energy shot or placebo) twice daily separated by approximately 7 hours for the first 7 days. This was followed by a washout period of 6 days and the alternate study drink was consumed for the final 7 days. A 12-lead electrocardiogram (ECG) was performed at baseline, 1, 3 and 5 hours on days 1, 7, 15 and 21. The automated ECG measurements were used for per-treatment and ITT analysis and analyzed using the paired t-test. RESULTS: A total of 24 subjects (29±5.8 years) were included for analysis. QTc values after consumption of a single placebo-dose were 414±18, 413±15, 413±19 and 417±19 milliseconds at baseline, 1, 3 and 5 hours respectively. Post consumption of a single 5 hour Energy dose, QTc values were 415±17, 408±19, 410±20, and 413±17 milliseconds at baseline, 1, 3 and 5 hours, respectively (all time matched inter- group p-values > 0.292). QTc values after consumption of placebo for 7 days were 415±20, 413±18, 409±19, and 413±22 milliseconds at baseline, 1, 3 and 5 hours, respectively. Post consumption of 5 hour Energy for 7 days, resulted in QTc values of 415±22, 413±24, 415±24, and 415±21 milliseconds at baseline, 1, 3 and 5 hours, respectively (all time matched inter- group p-values >0.198). There was no difference between the PR interval, QRS duration, QT interval and heart rate between the two groups. CONCLUSION: 5-Hour Energy did not induce any significant changes in the QTc interval or other ECG parameters after single and multiple doses throughout a 7 day period. These results may vary between different energy drinks due to the varying ingredients within them.

15. SUBJECT TERMS

US Air Force, Medical Service, Medical Research, Graduate Medical Education

16. SECURITY CLASSIFICATION OF:

a. REPORT

unclassified

b. ABSTRACT

unclassified

c. THIS PAGE

unclassified

17. LIMITATION OF
ABSTRACT

UU

18. NUMBER
OF PAGES

1

19a. NAME OF
RESPONSIBLE PERSON

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std Z39-18

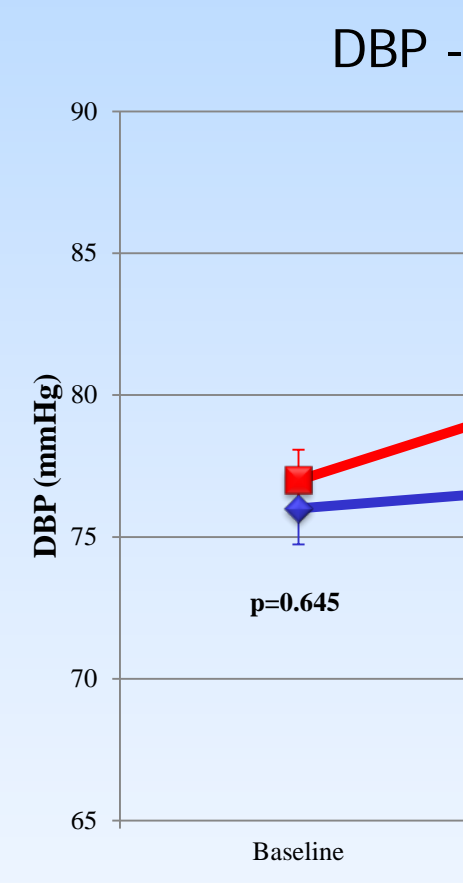
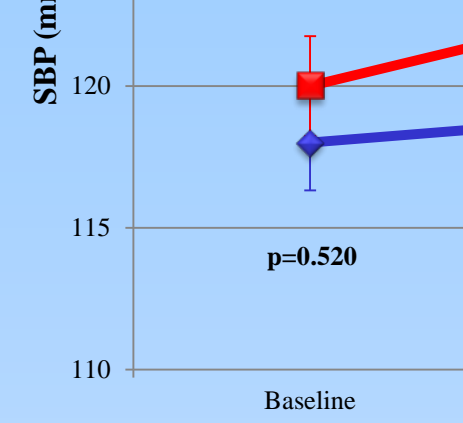
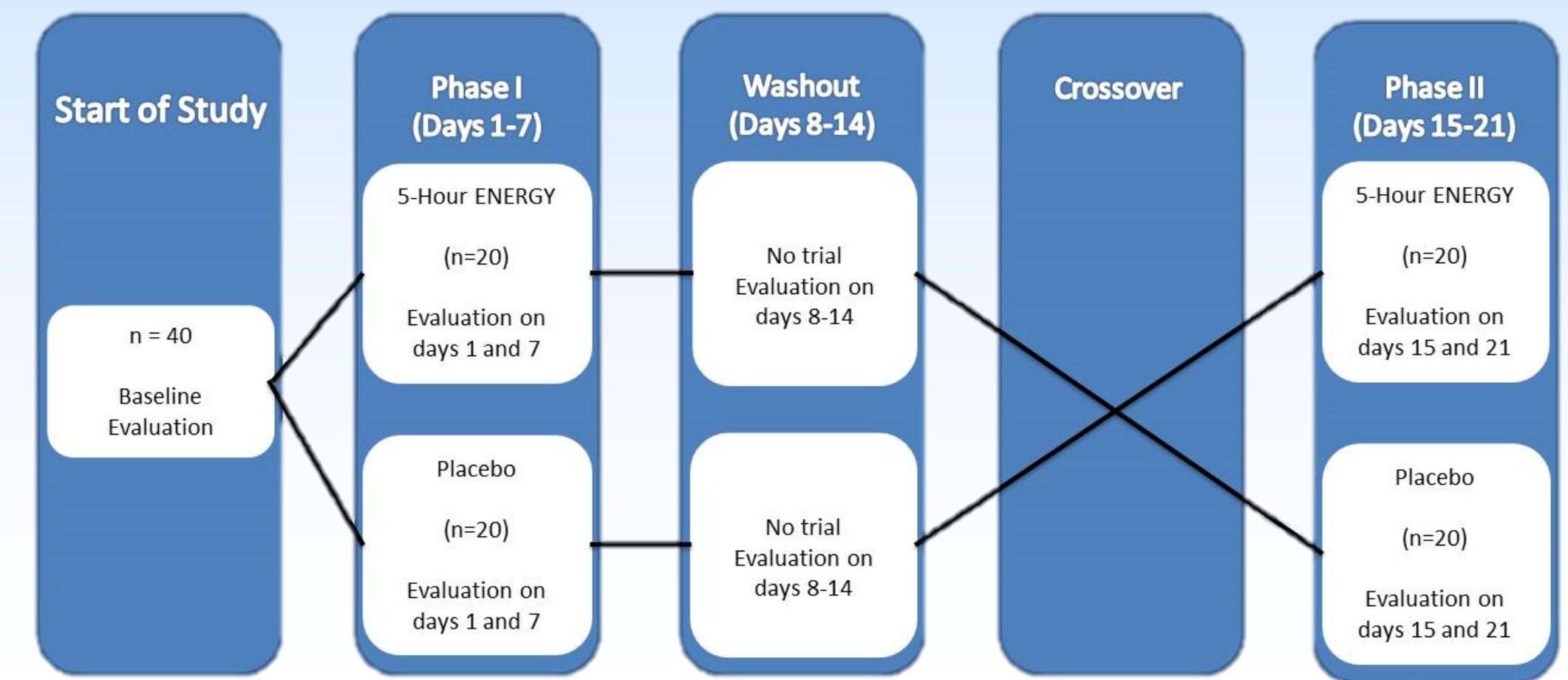
not on any medications. Subjects received the study drink (5 Hour Energy shot or placebo) twice daily separated by approximately 7 hours for the first 7 days. This was followed by a washout period of 6 days and the alternate study drink was consumed for the final 7 days. A 12-lead electrocardiogram (ECG) was performed at baseline, 1, 3 and 5 hours on days 1, 7, 15 and 21. The automated ECG measurements were used for per-treatment and ITT analysis and analyzed using the paired t-test.

RESULTS: A total of 24 subjects (29±5.8 years) were included for analysis. QTc values after consumption of a single placebo-dose were 414±18, 413±15, 413±19 and 417±19 milliseconds at baseline, 1, 3 and 5 hours respectively. Post consumption of a single 5 hour Energy dose, QTc values were 415±17, 408±19, 410±20, and 413±17 milliseconds at baseline, 1, 3 and 5 hours, respectively (all time matched inter- group p-values > 0.292). QTc values after consumption of placebo for 7 days were 415±20, 413±18, 409±19, and 413±22 milliseconds at baseline, 1, 3 and 5 hours, respectively. Post consumption of 5 hour Energy for 7 days, resulted in QTc values of 415±22, 413±24, 415±24, and 415±21 milliseconds at baseline, 1, 3 and 5 hours, respectively (all time matched inter- group p-values >0.198). There was no difference between the PR interval, QRS duration, QT interval and heart rate between the two groups.

CONCLUSION: 5-Hour Energy did not induce any significant changes in the QTc interval or other ECG parameters after single and multiple doses throughout a 7 day period. These results may vary between different energy drinks due to the varying ingredients within them.

baseline corrected QT (QTc) interval greater than 440 milliseconds (msec), concurrent use of drugs potentially interacting with either 5-Hour Energy drink or effecting electrocardiographic or hemodynamic parameters, or having consumed any type of energy drink within one week prior to randomization.

- Endpoints: QTc interval, office systolic blood pressure (SBP), office diastolic blood pressure (DBP), ambulatory SBP and DBP, PR interval, QRS complex duration and heart rate.
- Intervention: 2 shots separated by 7 hours of either 5-Hour Energy or matching placebo daily for 7 days.
- 12-lead ECG and office blood pressure were measured at baseline and at 1, 3 and 5 hours post consumption on days 1, 7, 15 and 21.
- Intergroup comparisons were performed using a paired student's t-test.



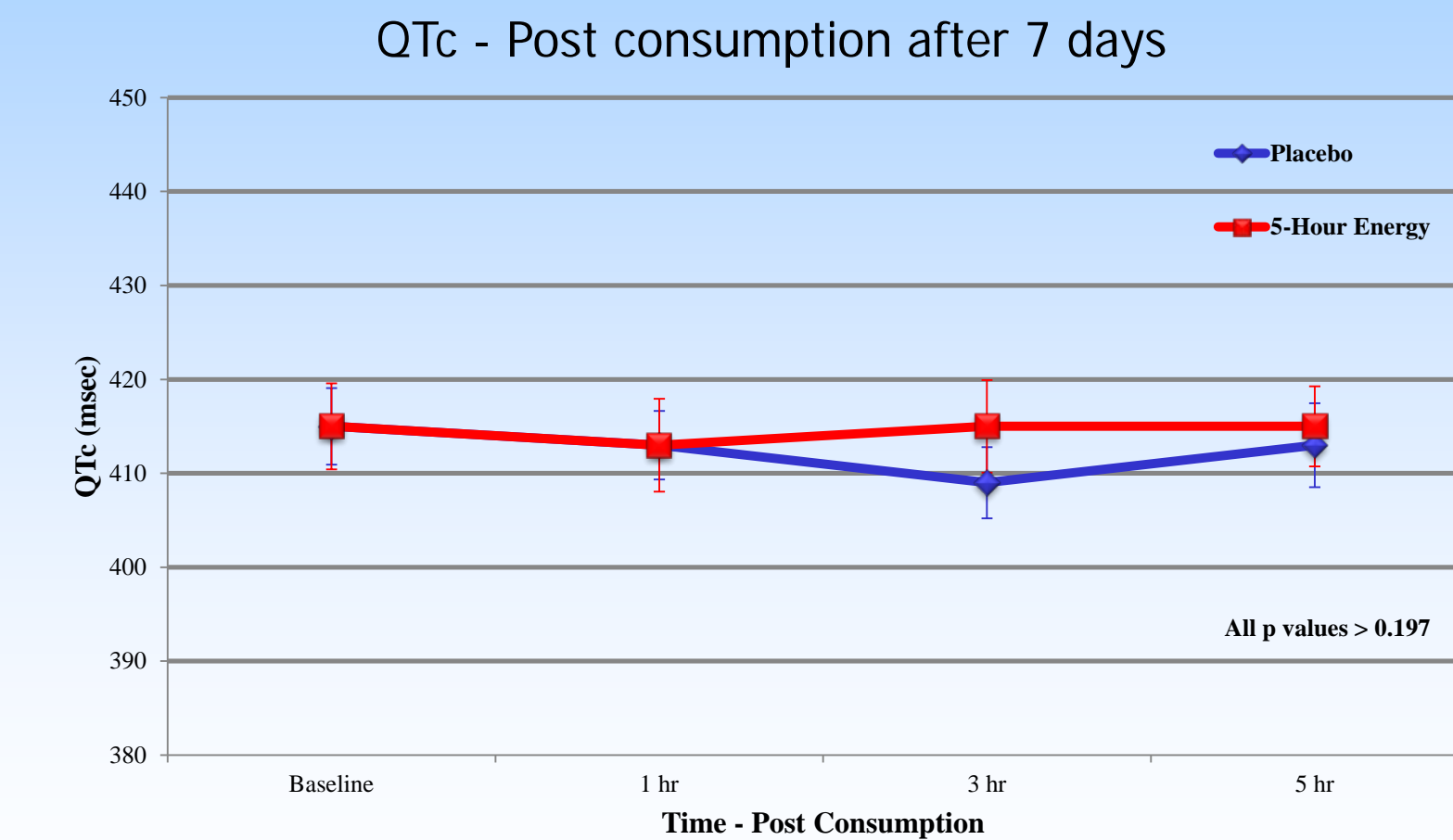
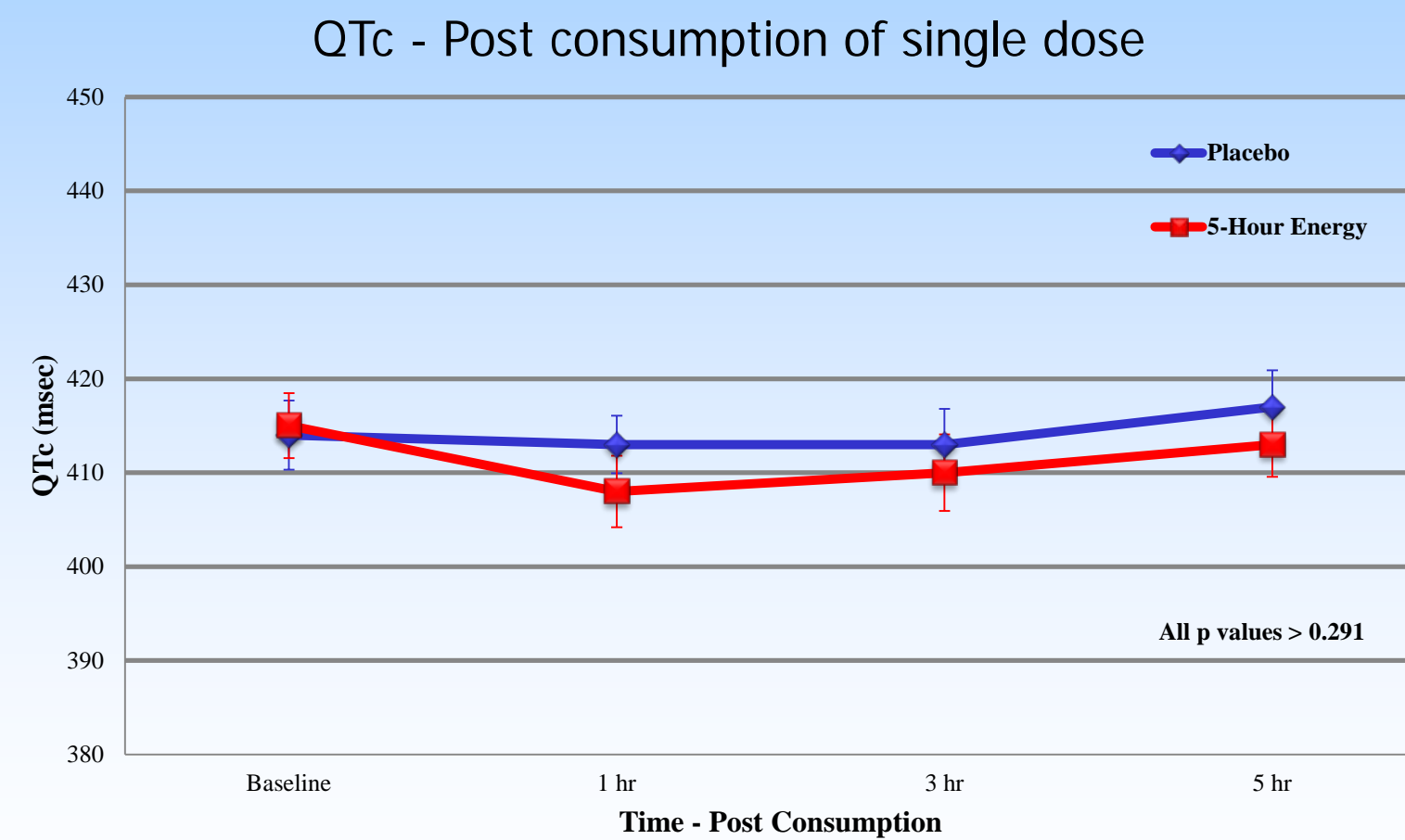
INTRODUCTION

- From 2008 to 2012, the market for energy drinks increased by 60%, resulting in sales of more than \$12.5 billion.
- The number of emergency department visits involving energy drinks has been steadily rising from 10,068 in 2007 to 20,738 in 2011. Of those visits, 58% involved only energy drinks while the remaining 42% involved energy drinks in combination with other substances.
- There have been reports of atrial fibrillation, Takotsubo cardiomyopathy and sudden cardiac deaths in healthy individuals after energy drink consumption.
- The FDA does not regulate nutraceuticals as rigorously as new drug entities and the safety of energy drink consumption needs further exploration.
- The goal of this study is to assess the acute and chronic effects of 5-Hour Energy consumption on electrocardiographic and hemodynamic parameters in healthy human subjects.

RESULTS

Twenty four subjects were included for analysis:

- Age: 28.4 ± 5.8 years
- Weight: 167.2 ± 30.1 lbs
- Height: 68.4 ± 3.6 inches
- Male: 77.8%
- Caucasian: 77.8%



Differences in

- 5-Hour Energy shot or post
- A single dose chronic cons
- Future studi doses, popu