**ABSTRACT**

**INTRODUCTION:** 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.
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Impact of Acute and Chronic 5-Hour Energy Consumption on Electrocardiographic and Blood Pressure Parameters

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A B S T R A C T

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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.

I N T R O D U C T I O N

• From 2008 to 2012, the market for energy drinks increased by 60%, resulting in sales of more than $22.5 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% included 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.

M E T H O D S

• This was a randomized, double blind, placebo-controlled, crossover study.
• This study planned to enroll 40 subjects.
  • Inclusion Criteria: healthy individuals between 18 and 40 years of age.
  • Exclusion Criteria: abnormal baseline cardiac rhythm, history of atrial or ventricular arrhythmia, baseline corrected QT (QTc) interval greater than 446 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, HR, QRS complex duration and heart rate.
  • Intervention: 2 shots separated by 7 hours of either 5-Hour Energy or Placebo.
  • Baseline 1 hr 3 hr 5 hr

R E S U L T S

Maximum post-dosing change from placebo Change (p-value)
QTc (Day 2) 1±1.6 msec (p=0.767)
QTc (Day 7) 8±2.0 msec (p=0.114)
Systolic blood pressure (Day 1) 4±5 mmHg (p=0.034)
Systolic blood pressure (Day 7) 3±5 mmHg (p=0.053)
Diastolic blood pressure (Day 1) 3±4 mmHg (p=0.031)
Diastolic blood pressure (Day 7) 3±4 mmHg (p=0.243)

Twenty four subjects were included for analysis:
• Age: 28.4±5.9 years
• Weight: 167.2±30.1 lbs
• Height: 65.2±2.5 inches
• Male: 77.8%
• Caucasian: 77.8%

Twenty four subjects were included for analysis of:
• QTc - Post consumption of single dose
• QTc - Post consumption of 7 days

CONCLUSIONS

• 5-Hour Energy did not significantly prolong the QTc interval or any other ECG parameters after a single shot or post 7 days of consumption.
• A single dose of 5-Hour Energy significantly increased SBP and DBP but the effects appear to diminish with chronic consumption.
• Future studies are needed to further assess the cardiac effects of energy drinks using differing products, doses, populations and duration of consumption.

This caveats expressed in this material are those of the authors, and do not reflect the official policy or position of the U.S. Government, the Department of Defense or the Department of the Air Force.