Data in Brief 10 (2017) 283–293

Contents lists available at ScienceDirect

Data in Brief

journal homepage: www.elsevier.com/locate/dib

Data Article

Biomarker of exposure level data set in smokers switching from conventional cigarettes to Tobacco Heating System 2.2, continuing smoking or abstaining from smoking for 5 days

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ARTICLE INFO

Article history:
Received 3 November 2016
Received in revised form
11 November 2016
Accepted 14 November 2016
Available online 18 November 2016

Keywords:
Reduced risk product
Tobacco exposure
Clinical study
Tobacco heating system 2.2

ABSTRACT

Levels of biomarkers of exposure to selected harmful and potentially harmful smoke constituents found in cigarette smoke, in addition to nicotine were measured in 160 smokers randomized for 5 days to continuing smoking conventional cigarettes (41 participants), switching to Tobacco Heating System 2.2 (THS 2.2) (80 participants), or abstaining from smoking (39 participants). The data reported here are descriptive statistics of the levels of each biomarker of exposure expressed as concentrations adjusted to creatinine; at baseline, and at the end of the study, and their relative change from baseline. Reductions in the levels of biomarkers of exposure when expressed as quantity excreted, are also reported. Detailed descriptions of bioanalytical assays used are also provided. The data presented here are related to the article entitled "Evaluation of the Tobacco Heating System 2.2. Part 8: 5-Day randomized reduced exposure clinical study in Poland" (Haziza et al., 2016) [1].

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http://dx.doi.org/10.1016/j.dib.2016.11.047

Specifications Table

Subject area	Pharmacology, toxicology, and pharmaceutical science
More specific subject area	Tobacco Harm reduction
Type of data	*Table, text*
How data was acquired	Liquid chromatography-tandem mass spectrometry, spectrophotometry, and gas chromatography–mass spectrometry.
Data format	*Analyzed*
Experimental factors	*Urine and blood sampling collected from healthy smokers participating in the clinical study. This study is disclosed on clinicaltrials.gov (*NCT01959932*)*
Experimental features	Measurements of biomarkers of exposure to selected harmful and potentially harmful constituents found in cigarette smoke and to to nicotine y after 5 days of use of THS 2.2, conventional cigarettes, or smoking abstinence.
Data source location	*Warsaw, Poland*
Data accessibility	*Data are within this article.*

Value of the data

- The product tested in this clinical study, the Tobacco Heating System 2.2 (THS 2.2), was developed by Philip Morris International (PMI) as a candidate reduced-risk product aiming to provide an acceptable alternative to CC smoking, replicating the ritual, taste, sensory characteristics, and nicotine uptake of conventional cigarette smoking.
- The data provide an understanding on how the levels of biomarkers of exposure compare in between smokers switching to THS 2.2 or smoking conventional cigarettes.
- The data may be of value to the scientific community because it offers further insights to other researchers in the context of tobacco harm reduction strategies.

1. Data

Table 1 describes the levels of 15 biomarkers of exposure to selected harmful and potentially harmful smoke constituents, along with the levels of biomarkers of exposure to nicotine, measured at baseline and after 5 days of the clinical study investigational period. Carboxyhemoglobin was measured in in blood (expressed as % of saturation of hemoglobin), nicotine and cotinine were measured in plasma (expressed in ng/mL), while the other biomarkers of exposure were measured in 24-hour urine (expressed as concentration adjusted to creatinine). Table 2 shows % of change from baseline within groups for each biomarker of exposure. Inferential analysis testing (ratio THS/CC expressed as %) using an ANCOVA model with adjustment to baseline values, sex, conventional cigarette consumption reported at screening, and study arms, is presented in Table 3.

2. Experimental design, materials and methods

This study was designed as a controlled, randomized, three-arm parallel, single-center study in confinement [1]. After the screening visit, the study included 1 day for admission, 2 days of baseline where smokers were smoking their own brand of CC, followed by a 5 day randomized investigational period distributed as follows: 41 subjects were randomized to continue CC smoking, 39 subjects were randomized to smoking abstinence, and 80 subjects were randomized to switch from CC to THS 2.2. At baseline and 5 days of the investigational period, blood and 24-hour urine were collected to measure 15 biomarkers of exposure to selected HPHCs. In addition, biomarkers of exposure to nicotine were assessed.