

DSMB Charter

Investigation of Cannabidiol for Reduction of NeuroInflammation in Chronic Back Pain

1R01DA053316-01

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NIH

A. Safety monitoring

An independent Data and Safety Monitoring Board (DSMB) will be appointed for this study, to assess the safety of the study by determining whether there is an unacceptable level of risk due to study procedures and whether an increased number of adverse events occur.

The DSMB will be established to analyze interim results to assess the safety of the trial at regular intervals for the duration of the study by determining whether an increased number of adverse events occur among study participants receiving drug compared to participants receiving placebo.

The board will include a statistician, a pain expert, and a psychiatrist. Each member of the DSMB will not otherwise be associated with the trial. Safety data will be reviewed by the Data and Safety Monitoring Board Data every 6 months after the recruitment period begins. The DSMB will receive summary reports on recruitment, retention and description of all adverse events and review them at each biannual DSMB meeting. The DSMB will receive all communication with the IRB. Subject information provided to the board will be identified only with study IDs to protect the confidentiality of subjects. The DSMB will assess interim results to determine whether the active drug treatment is associated with substantial risk, including higher rate of adverse outcomes when compared with the placebo group.

B. Outcomes monitoring

A DSMB Report written by the chair and approved by all members will be issued to the IRB after every DSMB meeting. The report will include, but may not be limited to, a synopsis of the trials, their progress to date, characteristics of participants enrolled, retention and disposition of study participants, quality assurance issues, regulatory issues, and reports of AEs and SAEs.

DSMB Role	Name and Title	Affiliation/ Institution	Contact Details	Summary of Expertise
DSMB Chair and Statistician	Bettina Hoepfner, PhD	MGH, Harvard Medical School	bhoepfner@mgh.harvard.edu	Statistician
DSMB Pain Expert	Jianren Mao, MD	MGH	jmao@mgh.harvard.edu	Pain physician

DSMB Psychiatrist	Esther Blessing, MD, PhD	NYU Grossman School of Medicine	esther.blessing@nyulangone.org	CBD, psychiatric disorders
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Trial investigators will not be members of the DSMB.