

# SAFETY OF DIMETHYL FUMARATE IN THE TREATMENT OF RELAPSING-REMITTING MULTIPLE SCLEROSIS: A RETROSPECTIVE STUDY

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## Background

Dimethyl fumarate (DMF) represents a new class of treatment for patients with relapsing remitting multiple sclerosis (RRMS). Scientific investigations are still in progress to clarify the ultimate mechanism of action responsible of the treatment effects of DMF. DMF does not have a single mechanism of action but rather has a multitude of biological effects. In vitro studies have revealed that DMF has anti-inflammatory properties linked to its ability to promote a Th2 immune response.

## Purpose

To evaluate safety profile of RRMS patients treated with DMF

## Material and methods

Retrospective observational study which included all patients >18-years old with RRMS. Recruitment period: 12-months. Patients were treated with 240 mg every 12 hours. Safety variable was described considering all patients who had to discontinue treatment due to significant adverse events affects to DMF. The information was obtained across of dispense program outpatient (Dominion®) from where they were collected: age, sex, diagnosis, treatment, dosage, adverse events and duration of treatment. Was drawn up a database.

## Results

43 subjects recruited (n=21), female percentage 73,4 %, mean age 44.3 [27-63]. The 24,4% of patients had to discontinue treatment. The mean treatment time to DMF discontinue of these patients was 6,2 months [0.5-24], producing an early discontinuation at week two in one patient. 27,2% DMF was discontinue due to flushing events, 63,3% due to gastrointestinal events and 18% due to linfopenia (Normal values: 710 - 4530/mm<sup>3</sup>). No changes were observed in the normal values of leucocytes or alanine aminotransferase and aspartate aminotransferase, during the study period.

## Conclusions

So far, two of the most relevant clinical trials about DMF in this pathology, "CONFIRMAR" and "DEFINIR", have proven to be a safe treatment. Data collected in our study show a high percentage of discontinuation, in disagreement with the clinical trials published. Although it is certain that a number of patients and longest periods of treatment are needed, in order to reach stronger conclusions.