Study title: Clinical Evaluation of Safety and Efficacy of Radio Frequency (Forma Eye) Treatment for Dry Eye Disease Due to Meibomian Gland Dysfunction

Date: May 2022

Identifiers: NCT04120584

Unique Protocol ID: DO609175A

Study Title	Clinical Evaluation of Safety and Efficacy of Radio Frequency (Forma Eye) Treatment for Dry Eye Disease Due to Meibomian Gland Dysfunction
Protocol Number	DO609175A
Sponsor	InMode Ltd.
Study Design	Prospective, open label, clinical study.
Planned Study Duration	Study duration including recruitment will be up to 12 months.
Investigational Device	Forma Eye handpiece
Planned Sample Size	At least 40 adult subjects with symptoms of evaporative dry eye/MGD
Subject Selection	Investigator will determine patient's eligibility to participate in the study according to inclusion/exclusion criteria.

Treatment and Duration	Eligible subjects will receive up to 3 treatments (2-3 weeks interval) with the Forma Eye Applicator according to the study protocol. Site#1: First 5 subjects will receive up to 3 treatments (2-3 weeks interval) Another 15 subjects will receive 1 treatment Site#2: 15 subjects will receive 1 treatment Site#3: 5subjects will receive 1 treatment The subject will return for 3 follow up visits: four weeks (4wk FU), 12 weeks (12wk FU), twenty-four weeks (24wk FU) after the last treatment.
Study Objectives	The objective of this trial is to evaluate the safety and efficacy of the Forma Eye Applicator for Symptoms of Dry Eye Disease Due to Meibomian Gland Dysfunction
Secondary Objective	The secondary objective of this study is subject satisfaction, as measured with a self-assessment questionnaire and a rating of device and procedure related adverse events.
Main Endpoints	Primary objectives will be measured using the next efficacy endpoints: • Mean change from baseline to prior to second, third treatments as well as four weeks (4wk FU), 12 weeks (12wk FU), twenty-four weeks (24wk FU) in Standardized Patient Evaluation of Eye Dryness (SPEED) • Mean change from baseline to prior to second, third treatments as well as four weeks (4wk FU), 12 weeks

	(12wk FU), twenty-four weeks (24wk FU) in Ocular Surface Disease Index (OSDI) • Improvement measurements using ocular surface fluorescent staining. NEI grading scheme grading for ocular surface staining score will be used in this study. • Changes from baseline to prior to second, third treatments as well as four weeks (4wk FU), 12 weeks (12wk FU), twenty-four weeks (24wk FU) in in Meibomian Gland Score (MGS), as assessed by a masked rater • Changes from baseline to prior to second, third treatments as well as four weeks (4wk FU), 12 weeks (12wk FU), twenty-four weeks (24wk FU) in Tear Break-Up Time (TBUT).
Secondary Endpoints	• Subject assessment of improvement based on 0 - 4-point Likert scale at four weeks (4wk FU), 12 weeks (12wk FU), twenty-four weeks (24wk FU) follow up visits. Improvement assessment will be performed independently by the subject himself on the following 0-4 points Likert scale questionnaire (Global Aesthetic Improvement Scale): 4 = Significantly marked improvement; 3 = Marked improvement; 2 = Moderate improvement; 1 = Slight improvement; 0 = No difference • Subject assessment of satisfaction will be filled-out by subjects only using 5-points Likert scale at four weeks (4wk FU), 12 weeks (12wk FU), twenty-four weeks (24wk FU) follow up visits: +2 = Very satisfied; +1 = Satisfied; 0 = Indifferent; -1 = Disappointed; -2 = Very disappointed • Safety assessment:

	○ The number, severity and type of any adverse event recorded throughout the study and post treatment (immediate and delayed response) ○ Discomfort assessment during the treatment using NSR scale
Statistical Methods	Descriptive statistics will be used to present changes in the assessments along the study course.

DATA ANALYSIS

Statistical analysis of all major factors will be performed to determine quantitatively the treatment efficacy.

The data will be analysed by the Sponsor using basic descriptive statistics, as well as comparison tests, where applicable. Treatment-related complications will be monitored and reported; if applicable, their incidence rate will be calculated and analysed for any relationship to treatment parameters.