

Efficacy test of micro-dosing with MistGo®

Conducted by Copenhagen University Hospital (Rigshospitalet) 2023

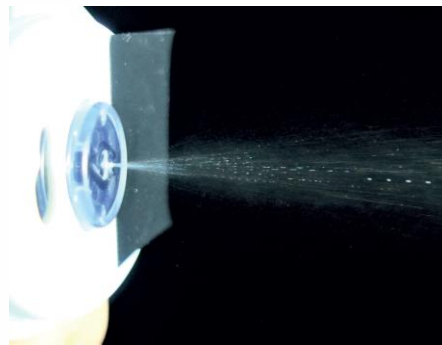


Background¹

- Medicating with an eye dropper result in a drop containing 30-50 μL which greatly exceeds the physiologic 6-8 μL ocular tear film capacity.
- A part of the delivered solution is washed out of the eye, but up to 80% of the dose enters the systemic circulation via transport into surface blood vessels or passage through the nasal lacrimal duct and into the digestive system, leading to an increased risk of systemic adverse events.
- Any excess solution remaining in the eye can lead to local adverse events, incl. hypersensitivity reactions to the drug or excipients.
- From a biopharmaceutical and economic point of view, the ideal would be to instill smaller volumes of eye medication as they can achieve a maximal tear film concentration with far less systemic absorption.
- Studies show that micro-dosing is as safe and efficacious as normal eye-drops.

MistGo® designed to micro-dose

- MistGo® contains a high-precision micropump, consistently metering a dose of 6 μL , dispensing no excess liquid to irritate the skin, enter systemic circulation or risk adverse events.
- The internal geometry of the nozzle is designed to vaporise the drug into a fine mist with a broad impact pattern, coating the entire cornea for optimal absorption (~10-12 mm diameter).



Mist of glaucoma medication latanoprost

Purpose & Methods

- Purpose:** to verify whether a micro dosing of 6 μL eye medicine delivered as a mist is comparable to a conventional eyedrop of appr. 30 μL of the same eye medication. Primary endpoint: pupil dilation degree.
- Method:** By use of a pupilometer the size of the subject's eye pupils were measured. A 6 μL mist dose of pupil dilation medicine Tropicamide 1% was given to each test subject's left eye by MistGo® test set-up. A drop of the same medicine was given to each test subject's right eye by a conventional eye drop bottle. Min 15 minutes after mist and drop instillation, the size of the subject's eye pupils was measured by use of pupilometer.

Results and Conclusions

- Successful dosing using the MistGo® test set-up was achieved in 100% of subjects in first attempt.
- Tropicamide treatment gave a significant pupil dilation for both eyes. There is no statistically significant difference in the obtained pupil dilations comparing treatment with a micro dose of 6 μL of Tropicamide 1% delivered as a mist to treatment with a conventional eyedrop of approximately 30 μL Tropicamide 1%.
- It can be concluded that MistGo® micro-dosing mist technology provides a comparable pupil dilation using Tropicamide 1% as when using a conventional eyedrop applicator.

