

TOPICAL IONIC CONTRA VIRAL THERAPY REDUCES SIZE AND HPV-LOAD OF CUTANEOUS WARTS IN A PROOF-OF-CONCEPT RCT

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INTRODUCTION

ICVT inhibits the K+ influx on which DNA viruses rely for replication and is therefore a potential novel treatment for cutaneous warts. A previous phase I/II open label trial showed ICVT to be safe and a consistent trend of wart size reduction after 7 days of treatment was already seen.

OBJECTIVES

- To assess efficacy of ICVT on wart size and HPV load after 6 weeks of treatment
- To evaluate activity of ICVT after 6 weeks of treatment and 4 and 8 weeks of follow-up by change in wart size, morphology and HPV load
- Safety and tolerability of ICVT

METHODS

- RCT, double-blind
- 80 patients
- ≥ 2 warts (common or plantar)
- Primary wart & all treated warts
- Four treatment arms: digoxin / furosemide (0.125%), digoxin (0.125%), furosemide (0.125%) or vehicle
- 42 days of topical application, once daily
- E-diary (app) for treatment compliance
- 8 weeks follow-up
- Wart size by caliper & 3D photography
- HPV load by swab

RESULTS

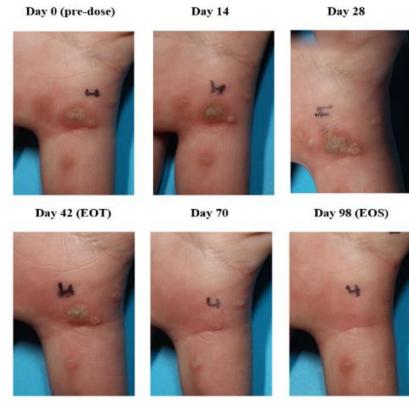


Figure 1. Photography assessments of a common wart from baseline to End of Study

- Demographics / baseline characteristics comparable among treatment groups
- Safe and well tolerated
- High treatment compliance (98% applied all doses)
- Clear trend of wart size reduction in all active treatment groups (table 1 and 2)

	Digo+Furo	Digoxin	Furosemide
	Vehicle	Vehicle	Vehicle
Diameter (mm), caliper	-2.5 (-4.92, -	-1.5 (-3.89, -	-1.05 (-3.44, -
	0.08)	0.89)	1.34)
	p = 0.0433	p = 0.2148	p = 0.3828
Diameter (mm), 3D	-1.79 (-3.39, -	-0.937 (-2.54, -	-1.09 (-2.67, -
	0.191)	0.662)	0.489)
	p = 0.0288	p = 0.2465	p = 0.1730

Table 1. primary analysis of change in diameter (mm) of primary warts from baseline to End of Study

	Digo+Furo	Digoxin	Furosemide
	Vehicle	Vehicle	Vehicle
Diameter	-3.02	-1.94	-2.12
(mm),	(-4.90, -1.13)	(-3.72, -0.17)	(-3.79, -0.44)
caliper	p=0.0019	p=0.0324	p=0.0136
Diameter (mm), 3D	-1.87 (-3.17,568) p=0.0052	-1.47 (-2.71,233) p=0.0203	-1.77 (-2.93,613) p=0.0030

Table 2. sensitivity analysis of change in diameter (mm) of all treated warts from baseline to End of Study

- ■Most pronounced effect after End of Treatment (fig. 1)
- Clear trend in HPV load reduction in all active treatment groups (fig.2)
- Strong correlation between wart size reduction and HPV load reduction

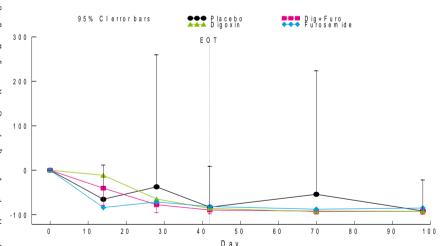


Figure 2. Change from baseline graph of any HPV in swabs of primary warts (% change)

CONCLUSIONS

The results of this study validates the proof of concept of topical ICVT with most pronounced effects on wart size and HPV load reduction when digoxin and furosemide are combined in a formulation, while the single active formulations showed efficacy as well.