Acceptability of an orodispersible film compared to syrup in neonates and infants - A randomized controlled trial

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Reliable pediatric pharmacotherapy in all age groups requires the availability of age-appropriate drug administration pathways. Orodispersible films (ODF) are a promising pediatric oral dosage form but to date there is a lack of reliable data on ODFs acceptability, swallowability and palatability, especially in very young children. ODFs would meet the targets: One dosage form matching the full range of pediatric patients, a minimum of non-toxic excipients, stable and easily to be produced.

The primary objective was to demonstrate non-inferiority in acceptability of a drug-free ODF in comparison to glucose syrup in children aged below one year. Secondary objectives were swallowability and palatability of the two formulations.

The study was performed in an open, randomized, two-way cross-over design with three age groups: 2 – 28 days, 29 days – 5 months, 6 – 12 months. 150 children (50 per age group) were randomized to the order of receiving the ODF (2 x 3 cm) and age-adapted amounts of glucose syrup (0.5 to 3ml). Deglutition and swallowing were assessed according to predefined evaluation criteria. The application of the formulations was video documented to evaluate the palatability.

The primary objective was confirmed: Non-inferiority of the acceptability of an ODF compared to syrup was clearly demonstrated and even superiority of the ODF could be shown. Also, the secondary endpoints demonstrated positive results including the superior swallowability of an ODF in comparison to syrup. The palatability assessments were in favor of the ODF.

ODFs are a promising and safe alternative to liquid formulations, even for very young children.

Biography

Viviane Klingmann is a Physician specialised in Paediatric and Adolescence Medicine at University Children's Hospital Düsseldorf. She started her research career with a thesis on developing methodology, research infrastructure and generation of statistically sound acceptability data for new paediatric galenic formulations (mini-tablets) in comparison to gold standard syrup. Her results enabled the acceptance of solid dosage forms in young children in the EMA guidelines on paediatric galenic formulations and formed the basis for the acceptance of mini-tablets in PIPs for different new drug developments. She continued performing clinical trials on testing the acceptability of different solid oral dosage forms.

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