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SUPERIORITY OF DESMOPRESSIN AS ORAL LYOPHILISATE FORMULATION COMPARED TO TABLET, RELATED TO LESS INTERFERENCE BY ASSOCIATED FOODINTAKE

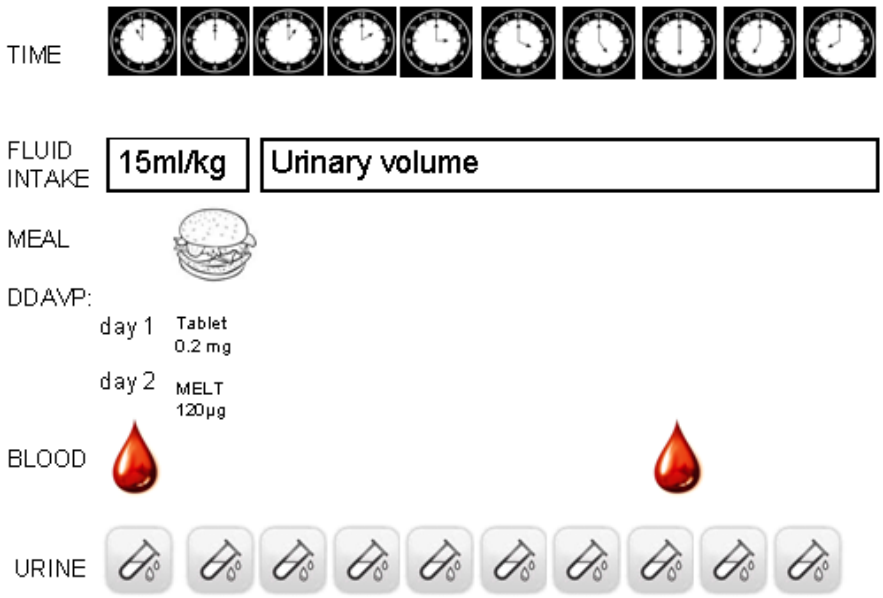
Hypothesis / aims of study

Desmopressin is a first-line treatment in MNE(Monosymptomatic Nocturnal Enuresis). The tablet 200µg and MELT (oral lyophilisate) 120µg are considered bioequivalent based on pharmacodynamic tests during oral water-load. In this study we compared pharmacodynamic data of desmopressin tablet and lyophilisate formulation, in addition to a standardized meal. This design allows extrapolation to clinical reality, where the time-interval for school-aged children between evening-meal and medication intake (one hour before bedtime) is limited. We hypothesize 1) a faster PD response and 2) a higher concentrating and 3) anti-diuretic activity for desmopressin MELT formulation compared to the tablet with simultaneous food-intake.

Study design, materials and methods

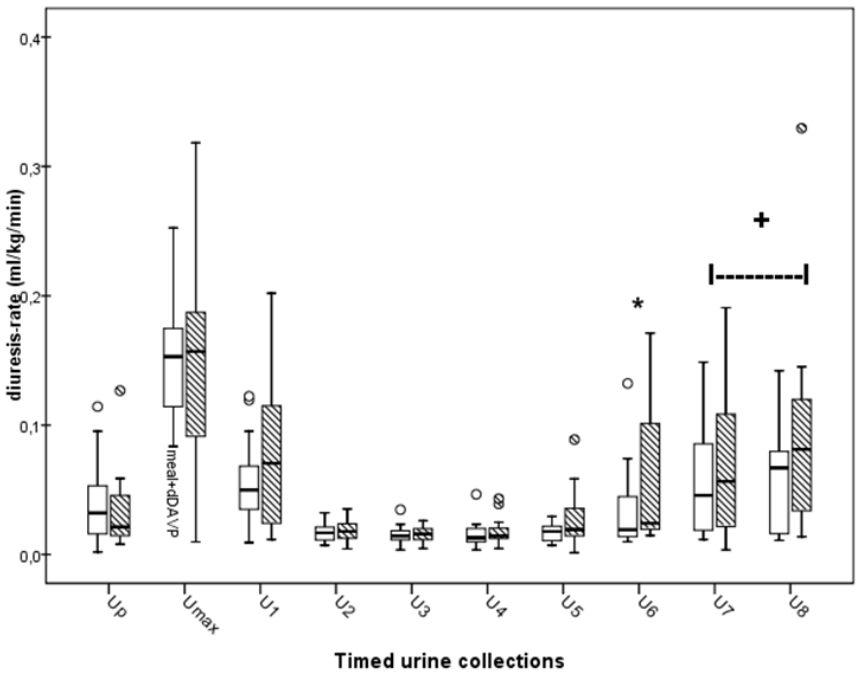
19 children (4F/15M) with MNE, partially responding to desmopressin tablet treatment were recruited in a tertiary centre, mean age 12.1y. Two tests were performed on separate days under identical, standardized conditions, starting with a 15ml/kg waterload. After achieving maximal diluting capacity, standardized meal was administered, followed by desmopressin tablet (T-test) or desmopressin lyophilisate /MELT (M-test) administration. Diuresis-rate was measured hourly, as well as urinary osmolality on every sample.

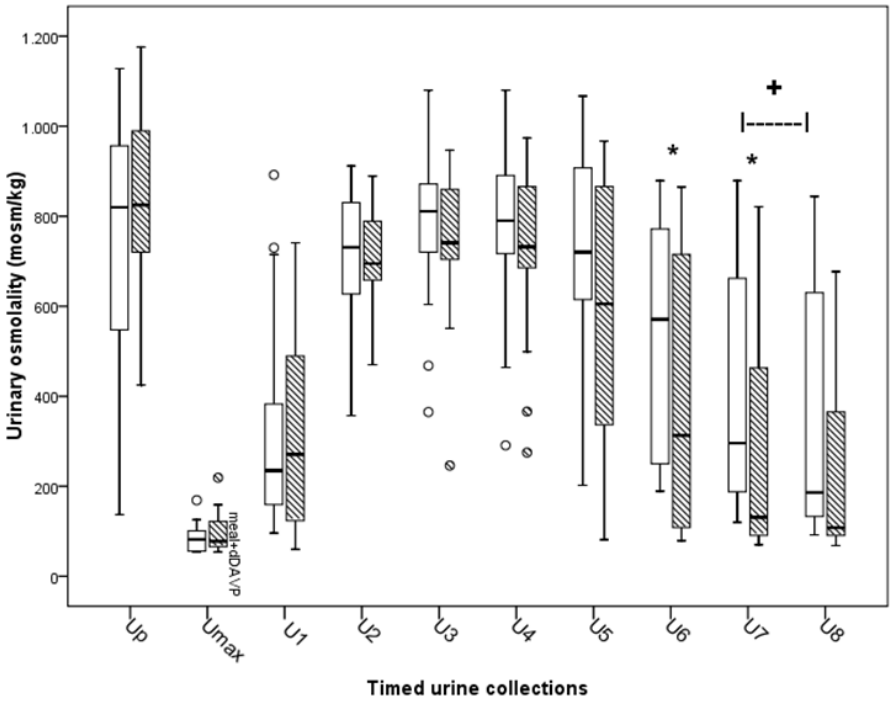
Fig 1.Study design



Results

All patients achieved maximal diluting capacity after oral water-load. In the early response phase more than 25 % of patients have a higher diuresis-rate with tablet compared to MELT and reached statistical significance in the plateau phase (U3-U5) and the duration of action (U5-U8) ($p<0.02$ and $p<0.005$ respectively) . For desmopressin MELT, overall smaller standard deviations in diuresis-rate are remarkable. Similarly, concentrating capacity demonstrated no significant differences in the early response- phase, in contrast with significant differences in the plateau phase and the duration of action ($p<0.036$ and $p<0.001$ respectively) .





Interpretation of results

In combination with a meal, desmopressin MELT formulation has a superior pharmacodynamic profile in comparison with the tablet, making it more suitable for the younger age group where time- interval between meal and drug administration is limited.

Specify source of funding or grant	**Investigator driven study funded by an unrestricted grant by Ferring International**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Eudract number 2009-017365-33**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics committee University hospital Ghent project 2009/653**

Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**