

## Abstract

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### **A randomised controlled trial of hypertonic saline nose drops as a treatment in children with the common cold (ELVIS-Kids trial)**

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There are 17.2 billion upper respiratory tract infections (URTI) cases per year with no effective antiviral treatments. Hypertonic saline (HS) provides chloride ions for intracellular hypochlorous acid production as an innate antiviral mechanism.

**Aim:** To investigate whether HS nose drops (2.6%) could reduce duration of illness in children age 0-6 years with a URTI.

**Methods:** Otherwise healthy children were recruited when well or within 48 hours of URTI onset and randomised 1:1 to parent delivered HS nose drops (3 drops per nostril,  $\geq 4$  times per day until well) or usual care (UC) at onset of URTI. A daily diary for 28 days captured compliance, side effects and symptoms (Canadian Acute Respiratory Illness and Flu Scale (CARIF)). Nasal mid-turbinate swabs (daily for 5 days) detected 17 URTI viruses by respiratory PCR panel.

**Results:** 407 children were randomised (206 HS, 205 UC) with intervention given to 301 who developed a URTI (HS 150, UC151). The HS group received a median of 5 days HS drops a median 3 times per day. Median duration of symptoms (DOS) was 2 days shorter with HS (HS 6 days, IQR 5-9, UC 8 days, IQR 5- 11,  $p=0.004$ ). DOS was reduced by HS where virus detected (HS  $n=102$ , median 6 days, IQR 5-8, UC 101, median 8, IQR 5-11,  $p=0.004$ ), but not where virus was not detected ( $p=0.9$ ). Rhinovirus the most common virus (HS  $n= 74/102$ , 73%). Fewer household contacts developed a URTI in the HS arm ( $n=66$ , 41%) vs UC ( $n=92$ , 58%),  $p=0.008$ . HS side effects of sneezing, runny nose and pain were infrequent and mild. No SAE.

**Conclusions:** In children with URTI, HS nose drops reduced symptom duration by 2 days and onward transmission with a good safety profile.