



RESEARCH

INFORMATION

Use of homemade hypertonic saline nose drops in children with the common cold: ELVIS Kids study



AIMS

Does the use of homemade hypertonic saline nose drops (i.e. salty water nose drops) in children (below 7 years of age) with the common cold reduce the duration of illness; duration & severity of individual symptoms; transmission within households; over-the-counter-medication use and wheeze?



KEY FINDINGS

In children who received hypertonic saline nose drops (HSND) [3 drops/nostril; minimum 4 times/day and up to 12 times/day, parents to adjust frequency depending on severity of symptoms], the following were significantly different compared to children receiving usual care (UC):

- Duration of illness was 2 days shorter.
- Duration of “runny nose”, “cough”, “not sleeping well”, “irritability”, “low energy” were one day shorter.
- Severity of “sore throat”, “irritability”, “feeling unwell”, “crying more”, “clinginess”, “unable to get out of bed” did not increase in those who received HSND unlike those who received usual care.
- Relative to the usual care, transmission within households was 25% lower
- Relative to the usual care, over-the-counter-medication (e.g., paracetamol, etc.) use was 31% lower.
- Rhinovirus was the commonest cause of infection (73%).
- Relative to usual care, episodes of wheeze in children with rhinovirus was 75% lower.
- Duration of illness and transmission within the households were further reduced when HSND were applied within 24 hours of symptoms.
- Side effects were generally few and mild
- Most parents (82%) considered HSND beneficial and (81%) said they would use it again.





WHAT DID THE STUDY INVOLVE?

- Children <7 years: randomly allocated to HSND or UC
- Parents: Taught to take nose swabs (5 consecutive days)
- HSND arm: Taught to make hypertonic saline and apply nose drops (3 drops/nostril: 4-12 times/day) until child was well.
- 4 times/day was the minimum. Parents were asked to increase frequency above 4 times based on severity.
- Study procedures started within 48 hours of cold symptoms
- Information was collected online, daily until end of illness and also 28 days after the cold started.

MAKING SALT WATER NOSE DROPS



WHAT WERE THE RESULTS AND WHAT DO THEY MEAN?

Duration of illness was 2-days lower in children who received HSND had compared to UC (median 6 vs 8 days, $P=0.004$). In the HSND arm, duration of “cough”, “runny nose”, “not sleeping well”, “irritability”, and “low energy” were a day lower compared to UC, which was significant. In the HSND arm significantly fewer children reported an increase in severity from baseline for “clinginess”, “sore throat”, “irritability”, “feeling unwell”, “crying more”, and “being unable to get out of bed”. The time to attain half the baseline severity was significantly lower in children who received HSND (Figure).

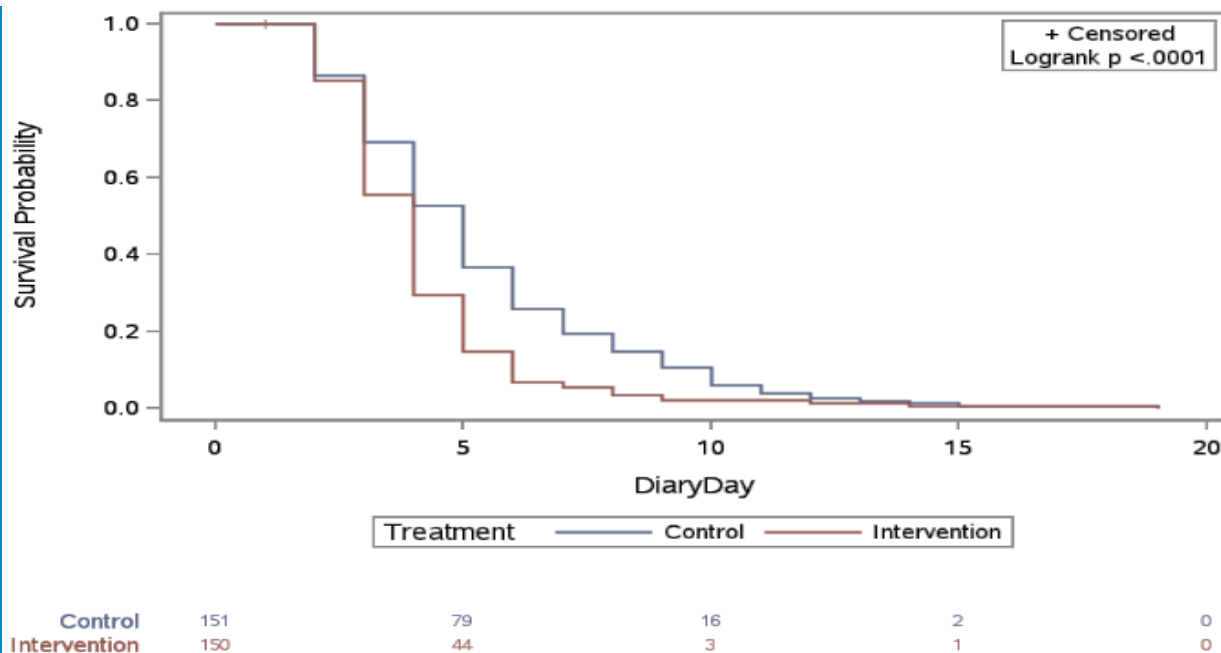




Time to reach half
the baseline
severity:

Blue line: Children
receiving Usual
Care

Red line: Children
receiving
Hypertonic Saline
Nose Drops



Fewer children (by 11%) who received HSND reported over-the-counter-medication use (HSND: 36/144; UC: 54/150; difference: -11%, 95%CI: -21.4, -0.6; $p=0.04$). Fewer HSND households (by 15%) reported household members developing URTI (HSND: 66/144, UC: 92/150; difference: -15.5%, 95%CI: -26.8, -4.2; $P=0.008$). Transmission was significantly lower when HSND were applied ≤ 24 hours of symptoms starting.

A virus was identified in 75% (203/272) of samples tested. Rhinovirus was the commonest (73%, 149/203). Fewer children with rhinovirus infection who received HSND had a wheeze [HSND: 3/66; UC: 12/66; difference: -13.6%, 95%CI: -24.2, -3.1; $P=0.01$].

Baseline viral shedding was significantly higher in those who joined the study and therefore collected swabs ≤ 24 hours [mean (SD): 4.28Log₁₀ (1.54)] compared to those who collected swabs >24 hours [mean (SD): 3.64Log₁₀ (1.74)] of symptom onset ($p=0.02$). Mean viral load was lower in the HSND arm on days 2 and 3, though the differences were not statistically significant.

HSND side-effects (scored 0-5) were generally mild and infrequent (sneezing: 6% (9/150) [median score 2.0, IQR (1.0-4.0)], runny nose: 19% (28/150) [median score 2.0, IQR (2.0-3.0)], and pain/soreness: 9% (14/150) [median score 0.5, IQR (0.0-2.0)]. Runny nose was expected as the solution is hypertonic, and parents were informed that the child may have some runny nose immediately after the drops. The fact that the duration of runny nose was a day lower in the HSND arm suggests that the side effect was temporary.

HSND were applied a median of 3 times/day (IQR: 2-4) for 5 days (IQR: 3-6 days). Parents reported delivering three drops/nostril per application. None in the UC arm reported using saline nose drops/sprays. Most parents (82%, 123/150) considered HSND beneficial and 81% (122/150) said they would use it again.





WHAT IMPACT COULD THE FINDINGS HAVE?

- Along with the knowledge that cells produce hypochlorous acid to stop virus multiplying inside it and the study in adults with the common cold, we can now say “we can treat the common cold”.
- Since parents made the nose drops at home with sea salt and easily available equipment (glass jars, dropper bottles, measuring spoons, kettle) the intervention can be easily rolled out to the community. Instruction videos are at <http://www.elviskids.co.uk/>. If parents are provided equipment and instructions as part of the “Baby Box Scheme”, they will be prepared for when their child has their first cold.
- The 75% reduction in wheeze in rhinovirus infected children who received HSND is promising and needs to be confirmed in a larger study as it could significantly reduce the burden on the NHS,
- As children who develop a wheeze due to rhinovirus are more likely to be diagnosed with asthma as teenagers, use of HSND in children could also reduce the burden of asthma in teenagers.



HOW WILL THE OUTCOMES BE DISSEMINATED?

The results have been presented at the European Respiratory Society (Vienna), Clinical Virology Network (Birmingham) and the Royal Society for General Practitioners (Liverpool) conferences. If CSO permits, we would like to present the work in conferences areas with limited resources (Asia/Africa).

The manuscript has been submitted. Once published, the link to the publication and a summary of the results will be provided on the trial website, on Edinburgh Clinical Trials Unit website and on clinicaltrials.gov. Results will also be publicised via social media and traditional news outlets.



CONCLUSION

Parent made and administered hypertonic saline nose drops is an effective intervention against the common cold in children. It reduces the duration and severity of illness. A minimum of 4 applications per day is recommended and increased by the parent up to 12 times/day based on symptom severity. Household transmission is also significantly reduced. The earlier the intervention, the better the response both in duration of illness and reduction in transmission. Wheeze following a rhinovirus infection is reduced by three fourths, which will have a significant impact on children and families. We can easily promote better child health by providing parents glass jars, dropper bottles, measuring spoons, instructions, and sea salt as part of the Baby Box Scheme in Scotland or similar schemes across the UK. Instructions and videos are at <http://www.elviskids.co.uk/>.



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